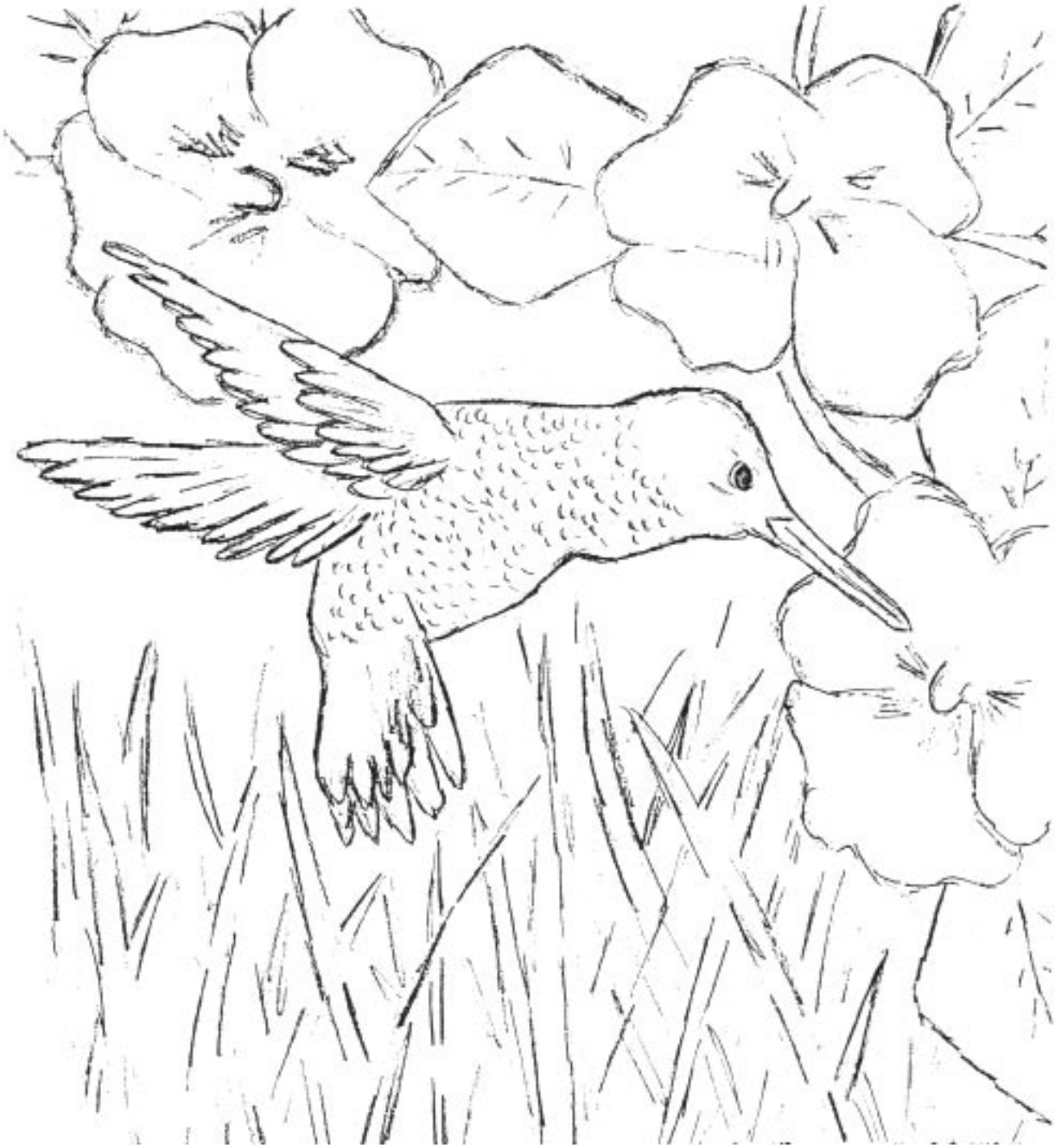
TEXAS REGISTER

Volume 21 Number 64 August 30, 1996 *Pages 8205-8335*



This month's front cover artwork:

Artist: *Korinne Kubena*

11th grade

East Bernard High School, Easte Bernard ISD

School children's artwork has decorated the blank filler pages of the *Texas Register* since 1987. Teachers throughout the state submit the drawings for students in grades K-12. The drawings dress up the otherwise gray pages of the *Texas Register* and introduce students to this obscure but important facet of state government.

Starting with the February 27, 1996 issue, we will display artwork on the cover of each *Texas Register.* The artwork featured on the front cover is chosen at random.

The artwork is published on what would otherwise be blank pages in the *Texas Register.* These blank pages are caused by the production process used to print the *Texas Register.* The artwork does not add additional pages to each issue and does not increase the cost of the *Texas Register.*

For more information about the student art project, please call (800) 226-7199.

Texas Register, **ISSN 0362-4781,** is published twice weekly 100 times a year except February 23, March 15, November 8, December 3, and December 31, 1996. Issues will be published by the Office of the Secretary of State, 1019 Brazos, Austin, Texas 78701. Subscription costs: printed, one year $95, six month $75. Costs for diskette and online versions vary by number of users (see back cover for rates). Single copies of most issues for the current year are available at $7 per copy in printed or electronic format.

The ***Texas Register*** is published under the Government Code, Title 10, Chapter 2002. Periodical Postage is paid at Austin, Texas.

POSTMASTER: Please send form 3579 changes to the ***Texas Register***, P.O. Box 13824, Austin, TX 78711-3824.

a section of the
Office of the Secretary of State
P.O. Box 13824
Austin, TX 78711-3824
(800) 226-7199
(512) 463-5561
FAX (512) 463-5569

Secretary of State - Antonio O. Garza, Jr.

Director - Dan Procter

Assistant Director - Dee Wright

Circulation/Marketing
Jill S. Ledbetter

Texas Administrative Code
Dana Blanton
Daneane Jarzombek

Texas Register
Carla Carter
Ann Franklin
Roberta Knight
Jamie McCornack
Mimi Sanchez
Patty Webster

Technical Support
Eric Bodenschatz

Receptionist
Elizabeth Stern

IN ADDITION

TEXAS ETHICS COMMISSION

The Texas Ethics Commission is authorized by the Government Code, §571.091, to issue advisory opinions in regard to the following statues: the Government Code, Chapter 302; the Government Code, Chapter 305; the Government Code, Chapter 572; the Election Code, Title 15; the Penal Code, Chapter 36; and the Penal Code, Chapter 39.

Requests for copies of the full texas of opinions or questions on particular submissions should be addressed to the Office of the Texas Ethics Commission, P.O. Box 12070, Austin, Texas 78711-2070, (512) 463-5800.

Ethics Adivsory Opinions

EAO-336. Whether a corporation may make candidates' campaign material available to corporate employees. (AOR-366).

Summary. A corporation that provides all candidates the same opportunity to make campaign materials available to corporate employees would not be making a campaign contribution. In this context "the same opportunity" means not only that all candidates must be given the opportunity to provide information, but also that the corporate communications to each candidate regarding the opportunity to provide information must be essentially the same and that the corporation must handle each candidate's information in the same way.

EAO–337. Whether the "revolving door" law prohibits a former employee of the comptroller from acting as legal counsel for a taxpayer in a "redetermination proceeding" that disputes the results of a sales tax audit the lawyer provided advice on while an employee of the comptroller. (AOR-373).

Summary. A sales tax audit and a redetermination proceeding in which the audit findings are disputed are part of the same "matter" for purposes of §572.054(b) of the Government Code.

EAO—338. Application of §305.026 of the Government Code and title 15 of the Election Code to a nonprofit corporation which includes various political subdivisions as dues-paying members. (AOR-376).

Summary. Section 305.026(a) of the Government Code places restrictions on the use of political subdivision funds to compensate a person who communicates with legislative officers or employees for the purpose of influencing legislation. Those restrictions do not apply to a political subdivision's payment of dues to an organization that uses the dues to pay a registered lobbyist.

EAO–339. Questions about the application of the Judicial Campaign Fairness Act to individuals seeking to fill vacancies in judicial offices. (AOR-377).

Summary. For purposes of calculating the fundraising period under §253.153(a)(1)(B) of the Election Code, a vacancy occurs on the date provided by §201.023 of the Election Code. A judicial candidate nominated under §202.006 of the Election Code to fill a vacancy in an unexpired term at the November general election may accept political contributions until 120 days after the November general election, regardless of whether the candidate has an opponent in the November election.

Issued in Austin, Texas, on August 22, 1996.

TRD-9612370
Tom Harrison
Executive Director
Texas Ethics Commission
Filed: August 23, 1996

♦ ♦ ♦

PROPOSED RULES

Before an agency may permanently adopt a new or amended section or repeal an existing section, a proposal detailing the action must be published in the ***Texas Register*** at least 30 days before action is taken. The 30-day time period gives interested persons an opportunity to review and make oral or written comments on the section. Also, in the case of substantive action, a public hearing must be granted if requested by at least 25 persons, a governmental subdivision or agency, or an association having at least 25 members.

Symbology in proposed amendments. New language added to an existing section is indicated by the use of **bold text**. [Brackets] indicate deletion of existing material within a section.

TITLE 31. NATURAL RESOURCES AND CONSERVATION

Part II. Texas Parks and Wildlife Department

Chapter 69. Resource Protection

Expiration Provision

31 TAC §69.81

The Texas Parks and Wildlife Department proposes the repeal of §69.81, concerning Expiration Provisions. All sections of 31 TAC Chapter 69, Resource Protection, will have been considered by the Parks and Wildlife Commission prior to the December 31, 1996 expiration date for sections within this chapter. These actions render this section redundant.

Dr. Bill Harvey, Regulatory Coordinator, has determined that for each of the first five years the repeal is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Dr. Harvey also has determined that for each of the first five years the repeal is in effect the public benefit anticipated as a result of the repeal will be removal of redundant sections of the Texas Administrative Code. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the repeal as proposed. The department has not filed a local impact statement with the Texas Employment Commission as required by the Administrative Procedure Act, §2001.022, as this agency has determined that the repeal will not impact local economies.

Comments on the proposal may be submitted to Dr. Bill Harvey, Executive Office, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744; (512) 389-4642 or 1-800-792-1112, ext. 4642.

The repeal is proposed under the authority of Parks and Wildlife Code, §§12.301-12.307, §43.027 and §68.014.

The Parks and Wildlife Code, §§12.301-12.307, §43.027 and §68.014 is affected by this proposed repeal.

§69.81. Expiration Provisions.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 19, 1996.

TRD-9612116
Bill Harvey
Regulatory Coordinator
Texas Parks and Wildlife Department
Earliest possible date of adoption: September 30, 1996
For further information, please call: (512) 389-4642

ADOPTED RULES

An agency may take final action on a section 30 days after a proposal has been published in the ***Texas Register***. The section becomes effective 20 days after the agency files the correct document with the ***Texas Register***, unless a later date is specified or unless a federal statute or regulation requires implementation of the action on shorter notice.

If an agency adopts the section without any changes to the proposed text, only the preamble of the notice and statement of legal authority will be published. If an agency adopts the section with changes to the proposed text, the proposal will be republished with the changes.

TITLE 1. ADMINISTRATION

Part IV. Office of the Secretary of State

Chapter 105. Solicitations

The Office of the Secretary of State adopts amendments to §§105.1, 105.4, 105.31, 105.34, 105.101, 105.131 and the repeal of §105.104 and §105.133 without changes to the proposed text as published in the July 2, 1996, issue of the *Texas Register* (21 TexReg 6049).

The amendments and repeals concern filing procedures for registrations filed under the Solicitation in the Name of Veterans Organization Act, Texas Revised Civil Statutes Annotated, article 9023b (Vernon Supp. 1996) and the Solicitations by Public Safety Organizations, Publications, and Independent Promoters Act, Texas Revised Civil Statutes Annotated, Article 9023c (Vernon Supp. 1996). These new rules provide for a more efficient filing system by clearly indicating dates when files must be properly completed. The new rules specifically indicate that if a file is not completed within the time allowed, the file will be closed and the filing fees forfeited.

No comments were received regarding adoption of these rules.

Subchapter A. Public Safety Solicitations

Public Safety Organizations, Public Safety Publications, and Certain Independent Promoters

1 TAC §105.1, §105.4

The amendments are adopted under the authority of Texas Revised Civil Statutes Annotated, Article 9023c (Vernon Supp. 1996), which require the Secretary of State to accept registrations filed under the act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 23, 1996

TRD-9612372
Clark Kent Irvin
Assistant Secretary of State
Office of the Secretary of State
Effective date: September 13, 1996
Proposal publication date: July 2, 1996
For further information, please call: (512) 475-0776

♦ ♦ ♦

Solicitors for Public Safety Organizations, Public Safety Publications, and Certain Independent Promoters

1 TAC §105.31, §105.34

The amendments are adopted under the authority of Texas Revised Civil Statutes Annotated, Article 9023c (Vernon Supp. 1996), which require the Secretary of State to accept registrations filed under the act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 23, 1996

TRD-9612373
Clark Kent Irvin
Assistant Secretary of State
Office of the Secretary of State
Effective date: September 13, 1996
Proposal publication date: July 2, 1996
For further information, please call: (512) 475-0776

♦ ♦ ♦

Subchapter B. Veterans Solicitations

Veterans Organizations

1 TAC §105.101

The amendment is adopted under the authority of Texas Revised Civil Statutes Annotated, Article 9023b (Vernon Supp. 1996), which require the Secretary of State to accept registrations filed under the act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 23, 1996

TRD-9612374
Clark Kent Irvin
Assistant Secretary of State
Office of the Secretary of State

Effective date: September 13, 1996
Proposal publication date: July 2, 1996
For further information, please call: (512) 475-0776

♦ ♦ ♦

1 TAC §105.104

The repeal is adopted under the authority of Texas Revised Civil Statutes Annotated, Article 9023b (Vernon Supp. 1996), which require the Secretary of State to accept registrations filed under the act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 23, 1996

TRD-9612375
Clark Kent Irvin
Assistant Secretary of State
Office of the Secretary of State
Effective date: September 13, 1996
Proposal publication date: July 2, 1996
For further information, please call: (512) 475-0776

♦ ♦ ♦

Solicitors for Veterans Organizations

1 TAC §105.131

The amendment is adopted under the authority of Texas Revised Civil Statutes Annotated, Article 9023b (Vernon Supp. 1996), which requires the Secretary of State to accept registrations filed under the act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 23, 1996

TRD-9612376
Clark Kent Irvin
Assistant Secretary of State
Office of the Secretary of State
Effective date: September 13, 1996
Proposal publication date: July 2, 1996
For further information, please call: (512) 475-0776

♦ ♦ ♦

1 TAC §105.133

The repeal is adopted under the authority of Texas Revised Civil Statutes Annotated, Article 9023b (Vernon Supp. 1996), which require the Secretary of State to accept registrations filed under the act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 23, 1996

TRD-9612377
Clark Kent Irvin
Assistant Secretary of State
Office of the Secretary of State
Effective date: September 13, 1996
Proposal publication date: July 2, 1996
For further information, please call: (512) 475-0776

♦ ♦ ♦

TITLE 4. AGRICULTURE

Part II. Texas Animal Health Commission

Chapter 35. Brucellosis

Subchapter A. Eradication of Brucellosis in Cattle

4 TAC § 35.4

The Texas Animal Health Commission adopts an amendment to §35.4, without changes to the proposed text as published in the June 18, 1996, issue of the *Texas Register* (21 TexReg 5503).

The amendment is necessary in §35.4 to remove the entry permit on all cattle entering Texas from Mexico except those sexually intact cattle moving to a premise for post-entry testing. The "S"-brand required on sexually intact cattle moving to a quarantined feedlot may be placed either prior to or upon arrival at the feedlot, and those cattle may be moved either to the feedlot or designated pen accompanied by a VS 1-27.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Texas Agriculture Code, Texas Civil Statutes, §161.081, which provides the Commission with the authority to promulgate rules regulating the movement of animals into the state, and §163.061, which provides the Commission with the authority to adopt rules relating to testing, vaccination, and movement of cattle into an area.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612188
Terry Beals, DVM
Executive Director
Texas Animal Health Commission
Effective date: September 30, 1996
Proposal publication date: June 18, 1996
For further information, please call: (512) 719-0714

♦ ♦ ♦

Chapter 41. Fever Ticks

4 TAC §41.1

The Texas Animal Health Commission adopts an amendment to §41.1, without changes to the proposed text as published in the June 18, 1996, issue of the *Texas Register* (21 TexReg 5504).

The amendment is necessary by removing language which has allowed cattle to move from an infected or exposed premise on three dippings without scratching, and by adding language which will allow movement from the premise with two dippings and a clean scratch on the last dipping.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Texas Agriculture Code, Texas Civil Statutes, Chapter 167, which provides the Commission with the authority to adopt rules to eradicate ticks.

The amendment implements the Agriculture Code, §167.003 and §167.029, which authorizes the Commission to adopt rules relating to eradicate ticks and to provide conditions for the handling and movement of livestock.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612189
Terry Beals, DVM
Executive Director
Texas Animal Health Commission
Effective date: September 30, 1996
Proposal publication date: June 18, 1996
For further information, please call: (512) 719-0714

♦ ♦ ♦

Chapter 43. Tuberculosis

Subchapter A. Cattle

4 TAC §43.1

The Texas Animal Health Commission adopts an amendment to §43.1, Cattle (All Dairy and Beef Animals), and Bison, without changes to the proposed text as published in the June 18, 1996, issue of the *Texas Register* (21 TexReg 5504).

The amendment is necessary to require branding on the left hip rather than the jaw, and to provide rules for the payment of indemnity for non-lesioned animals destroyed in compliance with the tuberculosis program or because of a test response.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Texas Agriculture Code, Texas Civil Statutes, Chapters 161 and 162 which provides the Commission with the authority to act to control and eradicate disease, and to prescribe the system of testing for bovine tuberculosis.

The amendment implements the Agriculture Code, §§161.041, 161.046, and 162.003.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612190
Terry Beals, DVM
Executive Director
Texas Animal Health Commission
Effective date: September 30, 1996
Proposal publication date: June 18, 1996
For further information, please call: (512) 719-0714

♦ ♦ ♦

4 TAC §43.2

The Texas Animal Health Commission adopts an amendment to §43.2, without changes to the proposed text as published in the June 28, 1996, issue of the *Texas Register* (21 TexReg 5917).

The amendment is necessary to provide for the movement of sexually intact cattle from a foreign county to a designated pen as well as to a quarantined feedlot and provide that movements to either destination be direct in a sealed truck and accompanied by a VS 1-27 permit with "S" branding required either prior to or on arrival.

No comments were received regarding adoption of the amendment.

The amendment is adopted under the Texas Agriculture Code, Texas Civil Statutes, Chapters 161 and 162 which provides the Commission with the authority to protect livestock against communicable diseases, including tuberculosis.

The amendment implements the Agriculture Code, §161.081 and §162.003 which authorizes the Commission to adopt necessary rules to regulate the movement of livestock into the state and to prescribe the manner, method, and system of tuberculosis testing.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612191
Terry Beals, DVM
Executive Director
Texas Animal Health Commission
Effective date: September 30, 1996
Proposal publication date: June 28, 1996
For further information, please call: (512) 719-0714

♦ ♦ ♦

Chapter 57. Poultry

4 TAC § 57.10

The Texas Animal Health Commission adopts an amendment to §57.10, without changes to the proposed text as published in the June 25, 1996, issue of the *Texas Register* (21 TexReg 5826).

The amendment is necessary to add Avian Encephalitis, and Paramyxovirus Disease other than Exotic Newcastle (VVND) to the list of reportable poultry diseases.

One comment from the Texas Poultry Federation was received in favor of adopting this amendment.

The amendment is adopted under the Texas Agriculture Code, Texas Civil Statutes, Chapter 161, which provides the Commission with the authority to adopt rules and sets forth the duties of this Commission to control disease.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612192
Terry Beals, DVM
Executive Director
Texas Animal Health Commission
Effective date: September 30, 1996
Proposal publication date: June 25, 1996
For further information, please call: (512) 719-0714

♦ ♦ ♦

4 TAC §57.11

The Texas Animal Health Commission adopts an amendment to §57.11, without changes to the proposed text as published in the June 18, 1996, issue of the *Texas Register* (21 TexReg 5506).

The amendment is necessary to eliminate the need for an Entry Permit to bring poultry into the State.

One comment from the Texas Poultry Federation was received in favor of adopting this amendment.

The amendment is adopted under the Texas Agriculture Code, Texas Civil Statutes, Chapter 161, which provides the Commission with the authority to adopt rules and sets forth the duties of this Commission to control disease.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612193
Terry Beals, DVM
Executive Director
Texas Animal Health Commission
Effective date: September 30, 1996
Proposal publication date: June 18, 1996
For further information, please call: (512) 719-0714

♦ ♦ ♦

TITLE 16. ECONOMIC REGULATION

Part II. Public Utility Commission of Texas

Chapter 23. Substantive Rules

Telephone

16 TAC §23.100

The Public Utility Commission of Texas adopts a new rule §23.100, relating to Electronic Publishing with changes to the proposed text published in the April 23, 1996 issue of the *Texas Register* (21 TexReg 3492). The rule sets out filing requirements for an incumbent local exchange company that is a separated affiliate of, or is participating in a joint venture with, an electronic publisher as these terms are defined by §274 of the Federal Telecommunications Act of 1996 (the Federal Act).

A public hearing on the amendment was held at Commission offices on April 30, 1996 at 10:00 a.m. Representatives from Southwestern Bell Telephone Company (SWBT) and the Office of the Attorney General (AG) attended the hearing. The AG made no comment on the record. SWBT's oral comments were largely reflective of their written comments and as such are summarized as follows.

The commission received written comments on the proposed rule from one party, SWBT. SWBT noted that the proposed rule referred to Title III, Subtitle L of the Public Utility Regulatory Act of 1995, relating to Electronic Publishing, for the definition of an "incumbent local exchange carrier," and stated that such a definition no longer fit any local exchange carrier in the state. An "incumbent local exchange carrier," as defined by Title III, Subtitle L of PURA, is ". . . a company . . . subject to the modification of final judgment . . ." which in turn refers to the 1982 antitrust Consent Decree which, SWBT stated, has been abrogated by the Federal Act. SWBT argued, therefore, that since there is no company that fits under the state's current definition for an incumbent local exchange carrier, Title III, Subtitle L of PURA was no longer applicable to any local exchange carrier in the state, and therefore the rule, too, had no practical application and should not be adopted. SWBT did offer, however, that the provisions of the Federal Act relating to electronic publishing are virtually identical to Title III, Subtitle L, of PURA and that any local exchange carrier operating in Texas that is subject to the provisions of the Federal Act would be complying with such provisions.

The commission agrees with SWBT that the definition of "incumbent local exchange carrier" cited by PURA 95 and the proposed rule is no longer applicable to any local exchange carrier operating in Texas, and that therefore the provisions of PURA 95 relating to electronic publishing (Title III, Subtitle L) do not apply to any local exchange carrier operating in Texas. In response to this comment, the commission has removed a significant portion of the text reiterating Title III, Subtitle L, of PURA 95, as well as all specific references to the Title, from the rule. Further, the rule has been clarified to define an "incumbent local exchange carrier," for purposes of §23.100 only, as "a company serving more than five million access lines in Texas."

The commission notes that PURA 95 provides the commission with the authority to require that a copy of any report filed by a public utility with any federal agency be filed with the commission, and therefore retains the essential reporting requirements addressed by the proposed text by referring to the Federal Act for identification of the appropriate documents to be filed, and by requiring an incumbent local exchange company to make such filings with the commission.

The commission further notes that §274(b)(4) of the Federal Telecommunications Act provides the commission with the

authority to require that an incumbent local exchange carrier that transfers any assets directly or indirectly from itself to a separated affiliate or joint venture, record such transactions in accordance with commission regulations to prevent improper cross subsidies, and therefore retains the language of the proposed rule related to such record keeping.

This amendment is adopted under PURA §1.101, which provides the commission with the authority to make and enforce rules reasonably required in the exercise of its powers and jurisdiction; and specifically, §1.202(a)(6) which provides the commission with the authority to require that a copy of any report filed by a public utility with any federal agency be filed with the commission, and §274 (b)(4) of the Federal Telecommunications Act, S. 652, which provides the commission with the authority to require that an incumbent local exchange carrier that transfers any assets directly or indirectly from itself to a separated affiliate or joint venture, record such transactions in accordance with commission regulations to prevent improper cross subsidies.

§23.100. Electronic Publishing.

(a) Definitions.

(1) The following words and terms, when used in this section, shall have the meanings set out in §274 of the Federal Telecommunications Act of 1996 (the Act), unless the context clearly indicates otherwise.

(A) affiliate

(B) control

(C) electronic publishing

(D) electronic publishing joint venture

(E) separated affiliate

(2) Incumbent Local Exchange Company means, for purposes of this section only, a company serving more than five million access lines in Texas.

(b) Incumbent local exchange company requirements. An incumbent local exchange company under common ownership or control with a separated affiliate or electronic publishing joint venture shall:

(1) value any assets that are transferred to a separated affiliate at the greater of net book cost or fair market value;

(2) value any assets that are transferred to the incumbent local exchange company by its separated affiliate at the lesser of net book cost or fair market value; and,

(3) file with the commission all filings made with the Federal Communications Commission (FCC) under §274 of the Act at the same time such filings are made with the FCC.

(c) Reporting. All reporting required by this section shall be filed in the commission's central records under project number 14506.

(d) Sunset. The provisions of this section do not apply to conduct occurring after February 8, 2000.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on August 20, 1996

TRD-9612129
Paula Mueller
Secretary of the Commission
Public Utility Commission of Texas
Effective date: September 10, 1996
Proposal publication date: April 23, 1996
For further information, please call: (512) 458-0100

♦ ♦ ♦

Part IV. Texas Department of Licensing and Regulation

Chapter 68. Architectural Barriers

16 TAC §68.91

The Texas Department of Licensing and Regulation adopts the repeal of §68.91 concerning Enforcement Authority of the Architectural Barriers program without changes to the proposed text as published in the July 16, 1996, issue of the *Texas Register* (21 TexReg 6556).

The section is being repealed to eliminate an unnecessary procedural step which generates significant administrative paperwork.

No comments were received regarding adoption of this repeal.

The repeal is adopted under Texas Civil Statutes, Article 9102, Architectural Barriers Act, which provide the Texas Department of Licensing and Regulation with the authority to promulgate and enforce a code of rules and take action necessary to assure compliance with the intent and purpose of the Act.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

Issued in Austin, Texas, on August 21, 1996.

TRD-9612173
Tommy V. Smith
Executive Director
Texas Department of Licensing and Regulation
Effective date: September 11, 1996
Proposal publication date: July 16, 1996
For further information, please call: (512) 463-7357

♦ ♦ ♦

TITLE 25. HEALTH SERVICES

Part I. Texas Department of Health

Chapter 117. End Stage Renal Disease Facilities

(Editors Note: Sections 117.41–117.45 were inadvertantly omitted from the August 27, 1996, issue of the Texas Register. Sections 117.1–117.3, 117.11–117.16, 117.31–117.34, 117.61–117.65, and 117.81–117.85 were published in the adopted section of the August 27, 1996, issue of the Texas Register and are being republished for clarity.)

The Texas Department of Health (department) adopts new §§117.1-117.3, 117.11-117.16, 117.31-117.34, 117.41-117.45, 117.61-117.65 and 117.81-117.85. Sections 117.2, 117.3, 117.11, 117.15, 117.31-117.34, 117.41, 117.43-117.45, 117.62, 117.63, 117.65, and 117.81 are adopted with changes to the proposed text as published in the April 12, 1996, issue of the *Texas Register* (21 TexReg 3120). Sections 117.1, 117.12, 117.13, 117.14, 117.16, 117.42, 117.61, 117.64, and 117.82-117.85 are adopted without changes and therefore will not be republished.

The new rules concern the licensing of end stage renal disease (ESRD) facilities. The sections cover purpose, definitions, licensing fees, application and issuance of temporary initial licenses, issuance and renewal of annual licenses, change of ownership, time periods for processing and issuing a license, inspections, optional plan review and inspection, minimal requirements for design and space, equipment, water treatment and reuse, sanitary and hygienic conditions, quality assurance for patient care, indicators of quality of care, provision and coordination of treatment and services, qualifications of staff, and clinical records. Also included are general requirements for dialysis technicians, dialysis technician training curricula and instructors, competency evaluation of dialysis technicians, documentation of dialysis technician competency, and prohibited acts for dialysis technicians. In addition, the sections address corrective action plans, appointment of temporary manager, disciplinary action, administrative penalties and recovery of costs.

The rules implement the Health and Safety Code, Chapter 251, as added by Acts 1995, 74th Legislature, Chapter 608 (House Bill 1023) effective September 1, 1995. The provisions requiring that ESRD facilities obtain a license in order to operate and that dialysis technicians be trained and evaluated for competency will become effective on September 1, 1996. The rules implement House Bill 1023 by specifying standards governing the issuance and terms of a state license to operate an ESRD facility (temporary initial, first annual, renewal and change of ownership licenses), the setting of fees for initial, renewal or change of ownership licenses, the facility's submittal of an annual report as a condition to renew a license, and inspections to assess compliance with the rules. In addition, the rules specify the qualifications and supervision of ESRD facility staff providing direct patient care, the equipment which is compatible to the health and safety of patients, factors contributing to and promoting sanitary and hygienic conditions, the criteria a facility must follow to maintain quality assurance for patient care and data indicative to quality of care being delivered, minimum standards addressing design and space for safe access and patient privacy, the information to be included and maintained in a patient's clinical record (including confidentiality), water treatment system components and parameters to assure safe water is used for dialysis, parameters for reuse of hemodialyzers if reuse is practiced by a facility, the training curriculum components for dialysis technicians and persons qualified to act as training instructors, information which serves as evidence that a dialysis technician has been trained and determined competent to serve as a dialysis technician, and the acts and practices that are allowed and prohibited to a dialysis technician. Finally, the rules address the department's use of a corrective action plan in collaboration with the ESRD Network of Texas Medical Review Board, the use of administrative penalties, the conditions under which the department may appoint a temporary manager, and the denial, suspension, or revocation of a license.

The department amended the proposed language based upon public comment and for clarification purposes. The changes made to §117.2 were for clarification purposes and include the addition of definitions for "advanced practice nurse," "charge nurse," "full-time equivalent," "intermediate level disinfection," and "physician assistant"; and amendments to the definitions for "dialysis," "dietitian," "social worker," and "supervising nurse." Changes made to §117.3 were to clarify that the change of ownership fee amount is contingent upon whether the department conducts an inspection for compliance with the patient health and safety provisions of the rules, as well as the inspection for compliance with the design and space provisions. The changes to §117.11 clarify that a facility operating prior to September 1, 1996, will train and evaluate for competency its dialysis technicians on staff prior to September 1, 1996 as required in §17.62 and §117.63; what is meant by the term "organizational structure" (§117.11(e)(6)), and that a fire inspection report indicating the facility meets local fire codes is a component of the initial application process (§117.11(e)(9)). Section 117.13 was amended to be clear that a change of ownership application must also include an approved fire inspection report issued by the local fire authority having jurisdiction (§117.13(c)). An amendment to §117.15(g) was made to address the transition of existing facilities in complying with certain sections of the rules. Section 117.15 and §117.81 were changed to eliminate confusion concerning the terms "plan of correction" and "corrective action plan" by deleting the term "plan of correction" and using the term "corrective action plan" throughout. The changes made to §§117.31-117.34, 117.41, 117.43-117.45, 117.62-117.63, and 17.65 are as a result of comments received concerning those sections; the reasons for these changes are described in the department's responses to these comments.

Concern was expressed by several commenters that the new rules would impose a financial burden that facilities could not meet. The department recognizes that the imposition of a new set of standards on ESRD facilities in Texas is not without costs. The new rules will require additional attention to patient needs in the form of increased staff, improved facilities and better trained staff. It was the opinion of several commenters that small, rural facilities in particular would bear an inordinate amount of the burden. Several went so far as to express an opinion that these facilities would be forced to close and patients, rather than benefiting from the new standards of care, would actually suffer because nearby facilities would close forcing them to travel longer distances for dialysis. This possibility was a cause for great concern. Accordingly, staff at the department solicited financial information from facility owners and managers. The intent was to obtain this information to determine whether or not the commenters were accurate in their assessment. Unfortunately, the data that was submitted was not sufficient to reach a conclusion. Facilities were justifiably reluctant to share competitive cost information. The issue, however, remained unresolved. In order to resolve this, the department obtained data on facility costs and revenues from a variety of sources: former facility administrators, clinicians (both in Texas and other states), federal officials, and others involved in the area of renal treatment and programming. This

data demonstrated the implementation of these rules would impact, but not eliminate facility profit margins. Recognizing that facilities must remain profitable to remain open, the department has amended two of the potentially costly requirements of the proposed rules, providing a phase-in period for the requirement that an registered nurse (RN) be present in the facility during all treatments and eliminating the staffing ratio for master's prepared social workers (MSW).

Concerns were expressed by many commenters related to the staffing of social workers. The requirement for a MSW mirrors the definition of social worker in the Medicare Conditions of Coverage, which has been in effect since 1976. The amended definition in the final rules includes a "grandfather" clause to allow those persons who were providing social services to ESRD patients before 1976 to continue in this capacity as long as consultation with an MSW is practiced, as is required by current Medicare regulations. Some commenters perceived that there were insufficient numbers of MSWs in Texas, particularly in the rural areas, and asked that the definition of social worker be broadened to include persons prepared at the bachelor's level in social work. Others presented substantial rationale that the MSW requirement be maintained.

To address these concerns, the department conducted a staffing survey to determine current MSW staffing in outpatient dialysis facilities and consulted with the board which licenses social workers to determine the actual number of MSWs in Texas. The staffing survey identified nine of 165 facilities reporting (out of 201 facilities polled) did not currently employ an MSW. The social worker licensing program reported there are currently 11,616 licensed MSWs in Texas. Review of the counties specified by commenters to have a shortage of licensed MSWs found, in each case, a significantly larger number of licensed MSWs than reported by the commenters. For example, commenters stated there were 28 licensed MSWs in the Valley; however, the counties of Hidalgo, Willacy, and Cameron alone have 141 licensed MSWs.

The final rules do not preclude the use of assistive personnel including persons with bachelor degrees in social work to perform discrete tasks in the provision of social services; therefore, the department has maintained the proposed qualification for a social worker, with the addition of identical language from the Medicare Conditions of Coverage which all facilities receiving Medicare reimbursement must follow. To address the concerns regarding the costs associated with hiring MSWs, the department eliminated the ratio requirement for one MSW to every 80 patients, placing the responsibility on the facility to provide adequate staffing to assure that the psychosocial needs of the patients be met.

The final area of concern addressed by many commenters involved the current and future function of licensed vocational nurses in outpatient dialysis facilities. The current Medicare Conditions of Coverage in effect since 1976, require only a licensed person to be present during dialysis treatment, and list the possible staff to fill this requirement to be registered nurses (RN), licensed vocational nurses (LVN), or physicians. The Conditions of Coverage are currently being revised by the Health Care Financing Administration (HCFA), and the proposed revised federal regulations require an RN to be present whenever dialysis is in progress. Many other commenters preferenced the need for RN presence at all times during dialysis treatment with information that outpatient ESRD facilities are treating an increasingly complex population, patients with higher acuity as they are discharged earlier from hospitals, and patients who are older and sicker with multiple co-morbidity factors. Forty percent of dialysis patients are diabetic and many of these have suffered amputations and blindness. The dialysis equipment has become more sophisticated, allowing the potential for rapid changes in a patient's fluid and chemistry status during treatment. Aside from the arguments related to education and experience, and to patient acuity expounded by many clinicians and patients, the statutory language did not exempt LVNs from the definition of a dialysis technician and requires dialysis technicians to be trained and to work under the supervision of an RN or physician. Further, the Nurse Practice Act does not allow for the delegation of patient assessment or professional nursing judgement. The LVN licensing act is a title protection act, does not contain practice provisions, or provide LVNs with delegation authority.

The department recognizes that there are increased costs in requiring an RN to be available to the treatment area at all times, and that there may not currently be a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules may diminish access to dialysis services and possibly force small businesses to close. Therefore, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The Board of Health charged the department to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes. The monitoring will include the collection of data through review of survey and complaint investigation outcomes and facilities' annual reports. The department welcomes partnerships with independent professional organizations in developing study protocols and examining the impact of these rules on patient outcomes.

In addition to the previously mentioned issues, the department has recently received questions concerning whether hospitals which provide dialysis treatment to patients in the hospital's skilled nursing facility (located within the hospital building) or patients admitted for less than 24 hours would be required to be licensed as a dialysis facility. The department's Hospital Licensing Director has indicated that hospital beds used for skilled nursing facility services for the purposes of Medicare certification, are for licensing purposes considered to be inpatient beds of the hospital regardless of how the Medicare program is billed for reimbursement. The Hospital Licensing Director has also indicated that patients who are admitted for less than 24 hours receiving dialysis in the hospital are not considered to be outpatients for licensing purposes. Therefore, a hospital which provides dialysis to these types of patients and does not provide routine, repetitive outpatient dialysis is not required to obtain an ESRD license. This program interpretation is subject to legal review by the department's Office of General Counsel (OGC) regarding this issue; a request from the department's Health Facility Licensing Division to the OGC for a legal opinion is pending.

The summary of comments received on the proposed rules and the department's responses are as follows.

Comment: Regarding the rules in general, five commenters stated that many of the proposed rules are a duplication of the Health Financing Administration (HCFA) requirements for dialysis facilities and therefore a duplication of regulations.

Response: The department disagrees that the rules are duplicative. The HCFA requirements relate to a facility's participation in a voluntary program and do not have the same applicability as do licensing regulations. In addition to the technical responsibilities related to the licensing of dialysis facilities, the Health and Safety Code, §251.014 makes the department responsible for monitoring the provision of dialysis treatment to Texans through the adoption of "minimum standards to protect the health and safety of a patient of an ESRD facility, including standards for the qualifications and supervision of professional staff, including physicians; the equipment used by the facility is compatible with the health and safety of the patients; the sanitary and hygienic conditions in the facility; quality assurance for patient care; the provision and coordination of treatment and services by the facility; clinical records maintained by the facility; design and space requirements for the facility for safe access by patients and personnel and for ensuring patient privacy; indicators of the quality of care provided by the facility; and water treatment and reuse by the facility." In addition, the Health and Safety Code, §251.032 requires that the department adopt "minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians; minimum standards for the determination of the competency of individuals who have been trained as dialysis technicians; minimum requirements for documentation that an individual has been trained and determined to be competent as a dialysis technician and the acceptance of that documentation by another end stage renal disease facility that may later employ the individual; and the acts and practices that are allowed or prohibited for dialysis technicians." These rules implement the statutory requirements. The department has based some of its rules on HCFA requirements to promote consistency with the federal rules which influence Medicare reimbursement and with nationally accepted standards for water and reuse, while also meeting the statutory mandate. The department cannot enforce a federal requirement as a state licensing requirement unless the requirement exists in the state licensing rules.

Comment: Regarding the rules in general, two commenters asked that the department consider delaying implementation of the rules.

Response: The department disagrees that implementation should be delayed. The Health and Safety Code, Chapter 251 requires all facilities currently operating to be licensed on September 1, 1996, and these facilities must be surveyed between September 1, 1996, and August 31, 1997. If a facility has not achieved compliance with the licensing requirements at the time of the survey, deficiencies will be cited and the facility will be expected to develop a corrective action plan. Implementation of the rules will begin September 1, 1996, with existing facilities provided a transition period that has been added in §117.15(g), and a three-year phase-in period has been provided in §117.44(c)(3) to allow an LVN to function as a charge nurse, allowing graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding the rules in general, one commenter expressed regret that the rules would not be implemented until September 1, 1996.

Response: The department understands the commenter's concern, but is restricted by the statute to not begin active enforcement of the rules any sooner than September 1, 1996. The department has, however, added language in §117.15(g) and §117.44(c)(3)to provide for transition periods for certain sections of the rules.

Comment: Regarding the rules in general, one commenter asked that the final rules not favor special interest groups or particular professions.

Response: The department agrees that the rules should not favor special interest groups or a particular profession. The department has made a great effort to solicit input and listen to the opinions of the renal community while developing rules to protect the health and safety of patients and remaining consistent with present standards promoting the quality of care, federal regulatory requirements for facilities participating in the Medicare program and other state laws. This effort was effected through public forums held in Austin, Arlington and Houston in November 1995, and mailouts to facilities, patients and their families and a variety of professional organizations. The input of each commenter during all stages of the rule-making process has been reviewed without prejudice.

Comment: Regarding the rules in general, four commenters expressed concerns that the industry could not bear the costs of implementing the licensing rules, and these increased costs were a threat to the availability of dialysis services in rural areas. One commenter stated that dialysis is a highly profitable industry.

Response: The department received estimates from the industry relating to the costs of implementing the proposed rules which ranged from $100,000 to $6,000,000. Methodology used to make these estimates was not completely explained, perhaps due to concerns about confidentiality regarding business information. The department received information relating to routine costs and reimbursements for dialysis services. The department recognizes that the composite rate has remained nearly fixed for several years, but also that there are additional sources of revenue for facilities, such as ancillary charges for drugs and bone density studies, and less obvious sources such as use of the vial overfill of costly medications. In reviewing the financial data provided, the department also recognizes that the rules will increase the costs to facilities, but the information received does not indicate that profitability will be eliminated. The legislature enacted the licensing statute and the department must promulgate standards to ensure the public health and safety of dialysis patients. In response to this and other comments, however, the department has changed certain staffing requirements which will reduce costs related to staffing.

Comment: Regarding §117.2, four commenters suggested adding a definition for "advanced practice nurse" to include the educational requirements specified by the Board of Nurse

Examiners and revising all references to these nurses in the rules to be consistent with the definition.

Response: The department agrees and has added a definition for "advanced practice nurse" in accordance with the Nurse Practice Act and revised the references to these nurses in §117.44(b)(4).

Comment: Regarding the rules in general, one commenter described an economic impact that the proposed rules and requirements will have on all dialysis facilities. The commenter stated that rural facilities have unique staffing problems for all positions and that it was difficult to find qualified staff. To illustrate, the commenter stated that the actual Medicare reimbursement has decreased since 1973 remaining constant until 1983 when the composite rates were reduced again. The commenter stated that the current composite rate is $95.00 to $118.75 per treatment which is what a facility uses to pay for the fixed and variable costs involved in the care and treatment of dialysis patients. The commenter indicated that the salary for an MSW at $33,600 would increase the cost per treatment for a 1 to 80 ratio by $3.00 per treatment and for a dietitian providing services to 100 patients and an average salary of $32,000 the costs per treatment would rise another $2.74. The commenter stated that although the additional staff will result in a higher quality of care for patients which is not unreasonable, the costs will definitely increase for facilities to provide this higher quality of care, and while large facilities can shift costs, the independent facility cannot and submitted that some of these costs are not totally necessary for quality patient care.

Response: The department acknowledges that the imposition of a new set of standards for facilities is not without costs. The new rules will require new attention to patients in the form of increased and better trained staff and improved facilities. The possibility of facilities closing is of great concern to the department; therefore, the department solicited financial information from facility owners and managers in order to determine the accuracy of assessments such as the commenter's. The information received was not sufficient to reach a conclusion and facilities were justifiably reluctant to share competitive cost information, leaving the issue unresolved. In order to resolve this, the department obtained data on facility costs and revenues from a variety of sources: former facility administrators, clinicians (both in Texas and other states), federal officials, and others involved in the area of renal treatment and programming. This data demonstrated the implementation of these rules would impact, but not eliminate facility profit margins. Recognizing that facilities must remain profitable to remain open, the department has made changes to two of the more costly requirements in the proposed rules. The final rules include a change in §117.43(e)(4) and a phase-in period in §117.44(c)(3)(A)-(D) relating to the charge nurse, and a change to §117.43(i)(5) eliminating the MSW staff-to-patient ratio. Additionally, the department has amended the ratios in §117.43(h)(5) for dietitians to provide some flexibility to facilities in developing staffing levels.

Comment: Regarding the rules in general, some commenters expressed concern that there were insufficient qualified RNs to staff all shifts in all dialysis facilities and that currently employed LVNs were performing charge responsibilities competently. These commenters continued that the increased costs to facilities which must discontinue using some LVNs and begin using all RNs could effect a negative financial impact to these facilities and possibly result in the closure of smaller facilities. Closure of the single facility in smaller communities would impede patient access to dialysis services. Other commenters stated that independently owned facilities or groups of facilities would not be able to absorb these increased costs and would be forced to sell their units to national chains.

Response: The department recognizes that there are increased costs in requiring an RN to be available to the treatment area at all times, and that there may not currently be a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules may diminish access to dialysis services and possibly force small businesses to close. Therefore, a definition of "charge nurse" has been added to §l17.2, referencing this exception and a three-year phase-in period has been provided in §117.44(c)(3) to allow an LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The Board of Health charged the department to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes.

Comment: One commenter acknowledged that "chief technician" and "dialysis technician" were defined in §117.2 and questioned why the technician who is strictly responsible for the water treatment and equipment was not also defined.

Response: The qualifications of the person responsible for water treatment are described in §117.44(f) relating to Qualifications of Staff. The purpose of defining a term in the definitions section is to clarify terms used multiple times throughout the document; the "technician responsible for water treatment" is not repeated in more than one section of the rules. Subsection 117.44(f) adequately describes the qualifications of the water treatment technician, and therefore the language was not changed.

Comment: Regarding §117.2, one commenter suggested that the definition of "dialysis" be corrected to include diffusion, osmosis and ultrafiltration and to delete the word "convection."

Response: The department agrees in part. The definition was changed to include diffusion, osmosis and ultrafiltration, but the term convection was not deleted because convection is a portion of the dialysis process.

Comment: Regarding §117.2, two commenters requested that LVNs be deleted from the definition of "dialysis technician." One commenter requested that different types of technicians (e.g., patient care, reuse, and water technicians) be recognized.

Response: The department agrees that LVNs and the different types of technicians should be recognized. However, the Health and Safety Code, Chapter 251 does not exclude LVNs in the definition of dialysis technicians. Therefore the department is not in a position to exclude LVNs from the definition in the rules. This restriction, however, does not preclude LVNs from providing vocational nursing as allowed by LVN licensing law. The department has recognized water and mechanical technicians in §117.44(f) and (g). Reuse technicians are recognized in §117.33(c)(1) via reference in the rules to the

reuse guidelines published by the American Association of Medical Instrumentation.

Comment: Regarding §117.2, one commenter requested clarification in the definition of "dietitian" as to what constitutes one year of experience for a dietitian and explained that registration may require clinical experience, depending on the educational level attained. One commenter requested that the definition be amended to clarify that the one-year clinical experience requirement could only be fulfilled after the individual was licensed or registered.

Response: The department agrees and added language to clarify that the year of experience is to be obtained subsequent to attaining eligibility for registration. The language was also added to §117.44(d).

Comment: One commenter indicated that §117.2 should include a definition for "direct care staff" and questioned whether this term includes such persons as the contract dietitian.

Response: The department disagrees and believes that the dialysis community understands that the term "direct care staff" includes those persons providing actual dialysis treatment, e.g. patient care technicians, LVNs, and RNs, and therefore did not add a definition of "direct care staff."

Comment: Regarding §117.2, one commenter suggested including a definition of "full-time equivalent" as all facilities may not use the same methodology to calculate this number.

Response: The department agrees and has added a definition to explain that for the purposes of determining staffing ratios under the licensing rules for ESRD facilities, one full-time equivalent equals 2,080 hours per 12 consecutive months.

Comment: Regarding §117.2, two commenters requested that "intermediate level disinfection" be defined; one of these commenters also asked that the term "terminal cleaning" be defined.

Response: The department agrees. A definition for "intermediate level disinfection," was added to §117.2 and the term "terminal cleaning" was deleted from the rules at §117.34(d)(2)(C)(iii) and (iv)(III).

Comment: Regarding §117.2, one commenter stated that the definition for "medical director" should require board certification in nephrology, without mention of board eligibility or experience as a director of a dialysis program.

Response: The department disagrees. The definition reflects the input of the renal community to accept current medical directors who are not board certified but whose experience in dialysis qualifies them for the position of medical director. The department does not believe that disqualifying current medical directors from continuing in their roles based solely on the fact that they do not hold board certification in nephrology would be in the best interests of the dialysis community.

Comment: Regarding §117.2, one commenter stated that the definition of "social worker" to have an MSW is unrealistic, citing difficulty in acquiring social workers even at the bachelors level, not to mention the MSW level.

Response: The department understands the commenter's concern. During the comment period, the department conducted a survey of current dialysis facility staffing. Two hundred one surveys were faxed out, 165 facilities returned the survey, for an 80% response rate. Of the 165 responders, nine facilities reported that they did not have an MSW available to provide services. The department believes that facilities should continue recruitment efforts to find MSWs, and encourages alliances between facilities, colleges and universities, and social worker organizations in recruiting qualified social workers. Given the complex psychosocial needs of many dialysis patients, the department believes that a bachelor's level social worker (BSW) has not received the training and education to provide psychosocial services, and has not changed the definition. Sections 117.43(i) and §117.44(e) do not prohibit BSWs from providing discrete services in the dialysis setting. Facilities may continue to utilize BSWs in providing services such as arranging transportation for patients to and from the facility and financial assistance. Further, the department recognizes that the Medicare Conditions of Coverage require the use of MSWs as social workers; the HCFA has only waived this requirement for individuals who were providing social services in dialysis facilities for one year before 1976. The department has amended the definition of "social worker" in §117.2 and the qualifications in §117.44(e) to be consistent with the HCFA regulations.

Comment: Regarding §117.2, two commenters expressed concern that the definition of "social worker" will have a negative effect on the provision of social work services to patients, particularly to patients who live in the rural areas of Texas.

Response: The department disagrees with the commenters and believes the requirement that an MSW be responsible for the delivery of social services to patients will have positive effects on patients. The delivery of social services described in §117.43(i)(2) cannot be provided by an individual other than an MSW. The social worker licensing program reports there are LMSWs in 179 of the 254 counties in Texas. Review of the listing by county finds LMSWs in many rural counties; there are 21 LMSWs in Angelina County for example. Facilities having difficulty in recruiting MSWs should reconsider their recruitment strategies, working conditions and salaries. Simply placing an ad in the local paper may not attract the notice of a potential candidate for a vacant MSW position; being required to cosign 200-300 patient record entries made by lesser prepared persons might not be as professionally rewarding as providing direct service to patients; and commenters have reported that MSWs are being offered the beginning salary of a BSW.

Comment: Regarding §117.2, one commenter proposed to change the definition of "social worker" to "a person who is currently licensed as a social worker or social work assistant under the Human Resources Code, Chapter 50 and who is regularly supervised by a social worker who is licensed as an MSW and who holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education."

Response: The department disagrees with the proposed change as it would not preserve the requirement for the MSW to provide direct services to each patient.

Comment: Regarding the definition of "supervising nurse" in §117.2, a commenter recommended that the ESRD experience for the supervising nurse be reduced from 12 months to six

months. One commenter requested that the definition for "supervising nurse" be consistent with the federal regulations.

Response: The department does not agree and has retained the requirement of 12 months experience in the last 24 months in the definitions at §117.2, but added language to allow certified nephrology nurses or certified hemodialysis nurses to substitute the current certification for the recent experience in hemodialysis. While the current federal regulations require a supervising nurse to have 18 months of experience as an RN with six months experience in dialysis, the publicized draft of the amended federal regulations expected to be proposed in the near future, require at least one year of experience in the nursing care of dialysis patients. The department chose consistency with the draft federal regulations and has not changed the language.

Comment: Regarding §117.2, 10 commenters asked that the definition of "supervising nurse" be amended to allow the facility to either meet the requirement or notify the department if a qualified nurse was not available to take the position.

Response: The department disagrees and has not changed the language. The commenters' suggestion does not explain the purpose of reporting inadequate staffing qualifications. The department has addressed what may be the commenters' concern by adding a three-year phase-in period in §117.44(c)(3) to allow an LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.2, one commenter supported the requirement of 12 months training in the definition of "supervising nurse," as this time will allow the non-renal nurse to acquire knowledge relative to renal disease and the principles of dialysis.

Response: The department agrees that the 12 months of experience in the dialysis setting is important prior to the nurse taking on the responsibilities of supervising other renal care staff and has retained the language.

Comment: Regarding §117.3(a), four commenters stated that the renewal licensing fees were excessive, should be less, or should not exceed the initial licensing fee; three of these four commenters stated that all the licensing fees were excessive. Two of these four commenters stated that the licensing fees should be $150 to $200 per license which is sufficient for the State of Rhode Island to operate its dialysis facility licensing program.

Response: The department disagrees with the commenters. The department is required to collect fees which are reasonable and necessary to operate the ESRD facility licensing program. The department's ESRD facility licensing program will not be funded by a source other than licensing fees. A $150 fee may be sufficient to generate total revenues for the State of Rhode Island to operate its licensing program regulating 11 facilities contained in an area the size of Harris County, Texas. By contrast, the number of ESRD facilities in the State of Texas totals 225 within a geographical area larger than the country of France. The operation of a licensing program is not limited to the review of a license application, fee and accompanying documents. On-site licensing inspections and complaint investigations are an integral and costly part of the licensing program and are funded from licensing fees. The department has established the fees based on the projected costs of the program to perform all the functions of licensing. As the licensing program is implemented and actual cost data is collected, the department will be better able to determine whether adjustment of these fee amounts is necessary to meet the statutory language and the department's responsibility to enforce the statute.

Comment: Regarding §117.3(a), two commenters asserted that licensing fees would make existing facilities less profitable and would discourage the development of new dialysis facilities.

Response: The department recognizes that the statutory requirement that the licensing program be fee-funded will be an annual expense to facilities. The department believes that the annual cost to a facility to pay the appropriate licensing fee is reasonable and necessary to operate the ESRD facility licensing program. In turn, the department will operate a licensing program to ensure the provision of safe and effective care of dialysis patients in Texas. The information the department has received related to cost/reimbursement data for the provision of dialysis services demonstrated that the annual cost to a facility as a result of paying the appropriate licensing fee is not an unreasonable burden to the profit margin in the ESRD industry.

Comment: Regarding §117.3(a)(3), one commenter asked why a design and space inspection would be needed for a change of ownership and not a health and safety inspection.

Response: The department agrees that this rule needs clarification and corrected the omission in §117.3(a)(3)(A) and (B) and §117.13(d). Either or both types of inspections may be conducted in the event of a change of ownership, depending upon the need and the discretion of the department.

Comment: Regarding §117.11, one commenter asked if each facility needs to apply for an initial temporary license, and if so, when is the application required and whether the temporary license is good for only six months.

Response: Every facility will need to apply for an initial temporary license beginning in July 1996. In August 1996, the department will be conducting workshops for ESRD facilities. Staff will be available and procedures set up to assist with completing the licensing applications and to potentially issue the initial temporary licenses at the conclusion of each of these workshops. Applications may also be returned to the Health Facility Licensing Division of the department by mail. Each current facility will need to have a temporary license by September 1, 1996. Each temporary license period is six months. A health and safety survey must be conducted before the initial annual license may be issued. For the initial year of the licensing program, approximately one-half of the facilities will be issued a second temporary license in March 1997, as the department will not be able to complete surveys of all current dialysis facilities within the first six-month period (September 1996 through February 1997).

Comment: Regarding §117.11(e), one commenter asked why a fire inspection report is not required for an initial facility, but is required for facilities renewing a license.

Response: The department agrees that this was an oversight and has added §117.11(e)(9) to require initial applicants to submit an approved fire inspection report from the local fire authority having jurisdiction over the facility that is dated no earlier than 12 months prior to the date of application. The department also added this language to §117.13(c), reorganizing the subsection for clarity, and to §117.13(d).

Comment: Regarding §117.11(e)(5), one commenter questioned if the requirement for the attestation regarding the completion of competency training for dialysis technicians refers to patient care technicians only.

Response: The notarized attestation refers to all dialysis technicians, as the term "dialysis technician" is defined in §117.2. Section 117.2 defines a "dialysis technician" as an individual who is not an RN or physician who provides dialysis care under the supervision of an RN or physician. This definition does not include mechanical or reuse technicians if these persons do not or will not provide dialysis patient care at any time. In addition, the department has amended the language at §117.11(e)(5) and §117.15(g) to clarify a facility's responsibilities to comply with the rules relating to dialysis technician training and competency evaluation.

Comment: Regarding §117.11(e)(5), one commenter expressed concern that new facilities will not have hired and completely trained all of their patient care staff at the time of their application, yet would be required to attest that the technicians had completed training by the time the facility begins providing service.

Response: The department disagrees with the commenter's interpretation of the rule language to mean that a facility may not receive a license until it can attest that it has dialysis technicians on staff who are trained and determined competent. The attestation in the rule language does not require the facility to have dialysis technicians on staff as a condition for licensure. The department recognizes that the patient care staff of facilities initiating dialysis services after September 1, 1996, may be limited at first to RNs and dialysis technician trainees under the supervision of an RN or physician until those trainees qualify as dialysis technicians. For these facilities, the attestation may simply state that the facility has no dialysis technicians on staff and is in the process of training or testing individuals as dialysis technicians in accordance with Subchapter E. The department believes that facilities may not allow untrained staff to function as dialysis technicians. A facility training individuals with previous dialysis experience would be using RNs for a minimum of two weeks until the trainee passes a written exam covering the required curriculum content and successfully completes a competency skills checklist. However, the department has amended §117.15(g) to address the transition of existing facilities in meeting the dialysis technician training requirement.

Comment: Regarding §117.11(e)(6), one commenter expressed uncertainty as to the meaning of "organizational structure" and asked the difference in this term and the "list of management and supervisory personnel."

Response: The department agrees that the rule needs clarification and has added language to clarify that the organizational structure refers to the facility's ownership structure. Language was also added to further describe the ownership information to be provided to the department.

Comment: Regarding §117.11(e)(8), one commenter questioned why the department should be involved in tax collection issues.

Response: The department is required to follow and enforce all state laws. This requirement is based on the Business Corporation Act, §2.45, which requires that licenses not be issued or renewed if a corporation is delinquent in payment of the franchise tax referenced in the Tax Code, Chapter 171.

Comment: Regarding §117.11(g) and (h), one commenter suggested that the presurvey conference and the design and space inspection be conducted at the same time.

Response: The initial surveys of existing facilities will not require a design and space inspection since they are "grandfathered" regarding those requirements. After September 1, 1996, the department's Health Facility Licensing Division Architectural Section will be responsible for design and space surveys of new facilities and new modifications or renovations. These surveyors are not qualified to provide guidance or answer questions concerning the other provisions of the rules, and thus could not provide the presurvey conference at the time of the design and space survey.

Comment: Regarding §117.11(g), one commenter asked if existing facilities would need to attend a presurvey conference. Another commenter asked for clarification as to the location of the presurvey conference and requested that the information be provided by phone or in writing.

Response: All facilities will be required to attend a presurvey conference. Department policy for presurvey conferences directs that these instructional sessions will normally be provided at the zone offices. However, the department has scheduled workshops which will serve as presurvey conferences on August 1, 1996, in Austin; August 6, 1996, in Arlington; and August 8, 1996, in Houston. Facilities unable to send representatives to one of these workshops will be required to attend a presurvey conference(s) which will be scheduled in a zone office after the needs are determined. The purpose of a presurvey conference is to ensure that facility representatives understand the requirements of these rules and have an opportunity to have questions answered in order to allow them to make corrections to planned operations and to prevent deficiencies at the survey. The average length of a presurvey conference for Medicare certification for a dialysis facility is three hours. While in some instances a presurvey conference might be conducted by phone, providing such information in writing would not allow the interchange of questions and answers, which is central to the concept of the presurvey conference.

Comment: Concerning §117.11(i), one commenter stated that this provision implies that the department has six months to issue a permanent license and expressed concerns that there would be unwarranted delays in licensing, and result in delays in certification. The commenter explained that facilities cannot operate if not certified for reimbursement by Medicare, thus a temporary license without certification would serve no purpose to the facility.

Response: A survey to ensure that the physical plant meets the minimum standards for design and space must be conducted for facilities completing construction after September 1, 1996. A temporary license will be issued at the successful completion of that survey. The health and safety survey to review the other minimum standards of these rules and the requirements for the dialysis technicians, cannot be conducted unless the facility has a temporary license. The department believes that the licensing and certification surveys will usually be conducted simultaneously; however, delays in initial certification survey federal funding may sometimes prevent the licensing surveyor from also performing the initial certification survey. State law, as of September 1, 1996, requires that all facilities which provide out patient dialysis be licensed. The department recognizes that the costs of providing dialysis compel Medicare certification, however there are no laws requiring facilities be certified. No change was made.

Comment: Regarding §117.12, one commenter supported the annual renewal of licenses for all outpatient centers to ensure that the intent of House Bill 1023 and the rules are maintained.

Response: The department appreciates the commenter's support. The licensing statute requires annual renewal of licenses as a condition for a facility's continued operation.

Comment: Regarding §117.12, one commenter expressed confusion regarding when the license will be due for renewal.

Response: The department recognizes and understands that the start-up of any licensing program may breed confusion. The staff of the Health Facility Licensing Division who are responsible for reviewing license applications and issuing licenses to ESRD facilities are also responsible for reviewing license applications and issuing temporary initial, annual and change of ownership licenses to approximately 3,500 ambulatory surgical centers, home and community support services agencies, hospices, abortion clinics, and birthing centers. Staggered license renewal dates are critical to distribute the workload evenly among a fixed number of department staff and to provide for a more timely issuance of licenses for all licensed facility types. The statute requires that the department issue a temporary initial license to all existing dialysis facilities effective September 1, 1996. The statute also requires that the temporary initial license period be for six months, and during this six-month period the department is required to conduct an inspection of each facility for determining compliance with the rules. The intent of the rule language in §117.12(b)(1) is to stagger the renewal dates of annual licenses so that all licenses do not expire the same day six months after issuance. Section 117.12(b)(1) provides that a first annual license expires one year from the date of a facility's successful completion of an initial inspection, instead of one year from the date the temporary initial license is effective. The rule language in §117.12(b)(1)(A) and (B) is intended to further assure sufficient staggering of expiration dates. For example, if you are an existing facility and your initial inspection occurs on September 10, 1996, your first annual license will expire on August 31, 1997 (the "last day of the preceding month of the next year"). If your initial inspection occurs on December 17, 1996, your first annual license will expire on December 31, 1997 (the "last day of the month of issuance of the next year"). Subsequent annual licenses for each of these example facilities will expire on that same date of the month each year thereafter. The department recognizes that during the first year, a facility's licensure period may be longer than the standard 12 months. No facility's licensure period during the first year of operation will be less than 12 months and the department will not assess an additional or prorated license fee to any facility for the benefit of a license extending beyond 12 months. This language in §117.12(b)(1) becomes void beginning September 1, 1997, at which time the expiration date of any first annual license will be based upon the issuance date of the temporary initial license (see §117.12(b)(2)).

Comments: One commenter recommended that the department consider and make allowances for "good causes" which would prevent a facility from making a timely application for renewal as is required in §117.12(i).

Response: The requirement in §117.12(i) informs a facility and the public that in accordance with the Administrative Procedure Act, Government Code, §2001.054 a license is no longer valid once it expires without timely application for renewal or once the license is amended, revoked, suspended, annulled, or withdrawn or the denial of a renewal becomes final. The department will send renewal notices to each facility no less than 60 days prior to the facility's license expiration date. The department has not experienced an irresolvable problem relating to the issuance of approximately 3,500 renewal licenses each year. The department expects each facility to submit the license application, fee and other required documents 30 days prior to its expiration date. The department also expects a facility to communicate with the department within a reasonable period of time before the license expires if a problem arises delaying the submittal of the application and fee. Many times, a circumstance perceived by a licensee delaying submittal of the license application is not really a cause to delay sending in the application. The department plans to continue the publication of periodic ESRD newsletters, and will use that vehicle to remind facilities of the need to renew licenses starting in September 1997. No change was made.

Comment: One commenter objected to the language in §117.12(j) relating to a facility's reporting to the department that it has ceased operations and returning the license certificate to the department.

Response: The department expects a facility to honor its commitment to operate as a dialysis facility as long as the facility holds a license to do so. The statute requires that each dialysis facility maintain a current license in order to operate.

Comment: Regarding §117.12(l)(4), two commenters stated that this requirement was unnecessary and should be deleted to reduce paperwork. One commenter stated that review of this data is busy work for the facility; the second commenter stated that this data should be reviewed by the governing body of the facility.

Response: The department disagrees. Since safe water for dialysis is critical to patient safety, the department believes that the information to be submitted is a reasonable mechanism to monitor a facility's ability to maintain safe water standards. The department does not plan to routinely conduct onsite surveys when additional stations are requested. The department does expect that a facility planning to expand will consider changes necessary to the water system to accommodate the expansion,

that the facility management will assure the product water from the revised water treatment system is cultured and analyzed, and that the medical director will review the results of such testing for acceptability. The submittal of this minimal data on water safety testing for department review is seen as the least intrusive manner to assure patient safety. No change was made.

Comment: Regarding §117.13, one commenter stated that federal regulations relating to change of ownership were sufficient without these requirements.

Response: The department understands the commenter's frustration to submit some of the same information to HCFA and to the department's ESRD licensing program. The department further understands that a misunderstanding exists between its responsibility to enforce the federal regulations adopted by HCFA in accordance with its contract with HCFA and its responsibility to enforce state licensing regulations in accordance with state law. The department cannot enforce a federal requirement as a state licensing requirement unless the requirement exists in the state licensing rules. Information provided to the HCFA for the purposes of Medicare certification is not necessarily available to the department for state licensing purposes.

Comment: Regarding §117.13(a), two commenters stated that transfers of licenses should be allowed.

Response: The department disagrees. The Health and Safety Code, §251.011 states that "a person may not operate an end stage renal disease facility without a license issued under this chapter." The department is responsible for identifying the "person" to whom the license is issued. An applicant for a license is responsible for the care provided in the facility. The prohibition to transfer a license described in §117.13(a) is important to identify the entity legally responsible for the operation of the facility. The rule does not prohibit the sale of the dialysis facility to another legal entity. The rule helps to ensure that a prospective new owner planning to accept the responsibility to care for dialysis patients also understands their responsibility to continue providing quality dialysis services. The rule further benefits the public by identifying the person who has accepted this responsibility.

Comment: Regarding §117.13(b), one commenter stated that a change in name should not require reissuance of a temporary license.

Response: The department agrees and directs the commenter to the second half of the sentence in §117.13(b) which allows for the simple revision of a licensee's name as allowed by law without constituting a change of ownership. The department also reminds the commenter that the license is not necessarily in the name under which the facility is "doing business as." A change in the facility's name is not the subject of §117.13.

Comment: Regarding §117.13(c), two commenters recommended reducing the minimum reporting time from 60 to 30 days.

Response: The department disagrees with the commenter's recommendation. The department needs sufficient time to receive, review and issue a license to the new owner to ensure no break in service occurs during the transition from the previous owner to the new owner. The recommended time frame of 30 days many times would provide the ESRD licensing program 14 days for these activities after the licensing program receives the application and documentation forwarded by department staff responsible for processing the licensing fee. The licensing program for ESRD facilities consists of a limited number of staff who also receive, review and issue licenses to approximately 3,500 other licensees per year. While some of the licensing program's procedures for the issuance of licenses have been automated, many others, such as the processing of fees, continue to require data entry. The department is working to further automate the licensing process and will revisit the minimum reporting time frame for changes of ownership at that time.

Comment: Regarding §117.14, two commenters stated that the time periods described should not exceed 30 days, and expressed concern that Medicare approval would be delayed without a fast turnaround on applications.

Response: The department disagrees. If the application is correct and complete when initially received, the maximum time period for processing is 45 days. Additional time periods are applicable only when the application is incorrect or incomplete. The licensing program for ESRD facilities consists of a limited number of staff who also receive, review and issue licenses to approximately 3,500 other licensees per year. While some of the licensing program's procedures for the issuance of licenses have been automated, many others, such as the processing of fees have not. The department is working to further automate the licensing process and will revisit the time periods for processing and issuing a license at that time.

Comment: One commenter stated that none of the causes listed in §117.14(c)(2) are sufficient to tolerate delays in the survey time frames; and stated that fees should be reimbursed if the deadlines were not met.

Response: The department disagrees because the time frames described in §117.14 relate to the processing of a license application, not the scheduling of surveys. The department recognizes that a survey is required prior to the issuance of a first annual license for the approximately 220 facilities currently operating, and has provided for the issuance of a second temporary initial license to those facilities who remain to be surveyed at the end of the first six months of licensure. These facilities will not need to submit an additional application for a second temporary initial license (if issued), and therefore, the time frames will not apply. Subsequent to the issuance of the temporary initial license, the time frames in §117.14 are applicable upon a facility's submittal of a renewal application or a change of ownership application.

Comment: One commenter stated that §117.14(a)-(c) gave too much direction to the state.

Response: The department disagrees. The Government Code, Chapter 2005 requires the department to set time frames for the processing and issuance of licenses. This section is designed to protect the facility and the department by categorizing responsibility should delays occur.

Comment: Regarding §117.15, one commenter indicated surveyors of the Joint Commission for the Accreditation of Health-

care Organizations (JCAHO) always looked at their hospital's dialysis operation.

Response: The department recognizes that JCAHO reviews hospital dialysis services as part of the hospital accreditation survey or an outpatient facility accreditation. While the JCAHO accreditation process includes an inspection of outpatient services, neither JCAHO nor any other accrediting agency has developed a survey process specifically for outpatient dialysis services. According to the JCAHO, outpatient dialysis services are reviewed under the JCAHO standards for general outpatient services. In addition, the licensing statute does not provide for "deemed status" by virtue of accreditation or Medicare certification; therefore, the department is not in a position to recognize such a status. A hospital which offers dialysis services only to its inpatients is not required to be licensed as an ESRD facility.

Comment: Regarding §117.15, seven commenters asked if there is a grievance procedure for a facility that believes that the surveyor is unfair.

Response: The department's Health Facility Compliance Division (HFCD) has a formal policy and procedure for complaints against surveyors. This is an internal policy for the HFCD; the language was not changed.

Comment: Regarding §117.15, one commenter replied that the term "plan of correction" needed to be defined better.

Response: The department agrees that there was confusion between "plan of correction" and "corrective action plan" in the rules and has deleted "plan of correction" in favor of using "corrective action plan" consistently in §117.15(b), (d), and (f), and §117.81.

Comment: Regarding §117.15, a commenter expressed concern that facilities receiving inspections during the first months after September 1, 1996, would not have had the time to staff in accordance with the rules when the final rules will not be available until after August 1, 1996.

Response: The department understands the commenter's concern. Therefore, the department has amended §117.15(g) and §117.44(c)(3) to address the transition of existing facilities in meeting certain rules and to describe the expectations of the department.

Comment: Regarding §117.15(c), one commenter recommended that a facility's annual report determine whether the department conducts an inspection.

Response: The department agrees and has changed the language to state that the department may request additional information or conduct an inspection of a facility after review of the facility's annual report.

Comment: Regarding §117.16, one commenter believed that although it is appropriate and helpful for the department to offer review of plans and specifications for new buildings or alterations, the facility requesting such review should bear this expense and it should not be part of the cost of licensing applied to all facilities in the state.

Response: The department agrees in principle, but there is no provision in the statute to allow separate fees to be collected for this service.

Comment: Regarding §117.31, one commenter suggested a medication room be required.

Response: The department disagrees. The rules do not prohibit the inclusion of a separate room for medication storage and preparation, but the department believes that requiring a medication room is beyond the department's statutory authority for developing rules for design and space. The statutory language restricts design and space requirements to those areas which assure safe access by patients and personnel and for ensuring patient privacy.

Comment: Regarding §117.31, one commenter requested that facilities already under construction before September 1, 1996, be exempt from the design and space requirements, as well as facilities waiting to begin operation because of delays in initial Medicare surveys.

Response: The department cannot change the statutory requirement which applies §117.31 to facilities that "initiate the provision of end stage renal disease services on or after September 1, 1996." The department's HFCD has worked with the industry and the HCFA to minimize delays in initial surveys for certification of ESRD facilities. Medicare certification is required for reimbursement for outpatient dialysis, but is not required to begin or continue to provide services. The statute is clear that a facility which initiates end stage renal disease services prior to September 1, 1996, is exempt from §117.31.

Comment: Regarding §117.31, one commenter asked that a clearer distinction be made regarding what areas will come under these regulations after renovation of a facility.

Response: The department directs the commenter to the language in §117.31(a)(1), which states that the section applies "to the area of a facility affected by design and space modifications or renovations completed after September 1, 1996."

Comment: Regarding §117.31(a)(3), one commenter suggested that the telephone number for the National Fire Protection Association may be incorrect.

Response: The department agrees and has corrected the telephone number.

Comment: Regarding §117.31(a)(4), four commenters suggested the department allow more flexibility in the placement of the reception counter or desk. The commenter stated that the reception desk should be accessible and in full view of the waiting room.

Response: The department agrees that the language was too restrictive and has made changes to provide greater flexibility for facilities. The language does not require that the reception counter or desk be a part of the waiting room.

Comment: Regarding§117.31(a)(4), 10 commenters stated it was not necessary to provide seating equal to the number of stations as many facilities provide staggered appointment times and all patients on a single shift are not in the waiting room at one time. Another commenter stated there was no need to specify the square footage of the waiting room.

Response: The department agrees and has deleted the specificity of numbers of chairs and size of the waiting room.

Comment: Regarding §117.31(a)(4), one commenter stated that the waiting room in a facility where he had been a patient was crowded.

Response: The department believes that requiring the facility to provide a separate waiting room with adequate seating will address this concern.

Comment: Regarding §117.31(a)(5), two commenters recommended the patient treatment area space be increased to 80 square feet, with one of these commenters stating 80 square feet would allow a safe distance from a neighbor's dialyzer; and the other commenter stating that 80 square feet would provide adequate distance for optimum infection control. Ten commenters recommended the patient treatment area space be decreased to 50 square feet. Another commenter stated that the patient treatment area requirements are high.

Response: The department disagrees and has retained the proposed 70 square feet and believes that this square footage provides for safe access and patient and staff safety. To address concerns that this requirement is too generous, the language was amended to allow inclusion of the aisles and counters in the 70 square feet.

Comment: Regarding §117.31(a)(5), one commenter stated the 70 square feet should include counters and aisles. Two commenters requested definitions of aisle and counter. One commenter of these commenters asked how big an aisle was and if a chase for the water supply to the machines would be considered a counter. Another of the commenters asked the department to define the number of feet allowed for an aisle.

Response: The department agrees and has amended the language to include aisles and counters in the 70 square feet. The architectural section of the Health Facility Licensing Division considers three feet eight inches as a recommended minimum aisle width. The department recommends that aisles be provided in front of the dialysis chairs and around the nursing station, to provide access to any emergency equipment, and for routes of egress. The plumbing chase for the water supply would be considered a counter.

Comment: Regarding §117.31(a)(6), 21 commenters supported a physically separate room for treating hepatitis B positive patients, with 18 commenters recommending that the rules be consistent with recommendations of the Centers for Disease Control (CDC) for the control of hepatitis in the dialysis setting, and one stating that using merely separate areas would not serve the purpose of decreasing the risk of hepatitis exposure.

Response: The department agrees with the commenters and has revised the language at §117.31(a)(6) to be consistent with CDC recommendations for a separate room for hepatitis B positive patients. The department has addressed universal precautions in §117.34(a)(1), environmental infection control in §117.34(b), and hepatitis B prevention in §117.34(d) as additional safeguards in preventing the spread of hepatitis B in a dialysis facility.

Comment: Regarding §117.31(a)(7), one commenter proposed that the department substitute a requirement that patients be within vision of staff or family member at all times, and believed that an audible alarm would be more effective that a visual alarm. A second commenter recommended that the requirement be just a call light.

Response: The department disagrees. Requiring the patient to remain within sight of staff or a family member at all times would not afford for patient privacy in the restroom, for example. The system described by the proposed rules was not changed.

Comment: Regarding §117.31(a)(8), 11 respondents commented that gender specific bathrooms is an unnecessary expense. Another commenter requested "grandfathering" the requirement for gender-specific restroom for staff and patients.

Response: The department agrees in part. The department has deleted the requirement for gender-specific restrooms for all facilities. A "grandfathering" provision is not necessary because the requirement relating to restrooms applies only to facilities initiating services on or after September 1, 1996.

Comment: Regarding §117.31(a)(8), one commenter stated that there are no power vents in toilets in dialysis facilities.

Response: Because the statutory language restricts the rules in this subsection to safe access by patients and personnel and for ensuring patient privacy, the department did not address ventilation systems for toilets. For restroom ventilation specifications, facilities will be expected to comply with local building codes and fire ordinances.

Comment: Regarding §117.31(a)(10), four commenters stated that this standard was too restrictive, and that more flexibility in the size and components of this room should be allowed. Another commenter stated that an exam room requirement as part of a dialysis facility is not necessary.

Response: The department agrees that more flexibility is needed and reworded the standard deleting the square footage and room arrangement requirements. However, in order to ensure patient privacy, there must be a room to allow medical examinations away from the treatment area. The department retained the requirement for an exam room.

Comment: Regarding §117.31(a)(11), one commenter requested that telephone access be available in the treatment area and waiting room for patients and family members. Another commenter stated there was only one phone in their facility.

Response: The department agrees that telephone access should be provided but has not changed the rule to specify where access will occur. Section 117.31(a)(11) requires that facilities provide telephone access to patients and family members in the facility. There is no intent to specify how many phones must be available. The intent is that the patient or family would be allowed to use the phone upon request. There is no requirement for a separate or additional phone for patients or families.

Comment: Regarding §117.31(a)(11), one commenter stated the provision of telephone service to patients and their families has nothing to do with the provision of safe and adequate dialysis treatments and should not be the concern of the department.

Response: The department disagrees. Providing access to a telephone relates to patient privacy. The department retained the requirement.

Comment: Regarding §117.31(a)(14), a commenter from a facility which provides on-going, in-center peritoneal dialysis treatments requested that the distinction between training and providing treatments be made clear, and that a separate room for providing treatments not be required.

Response: The department agrees and reworded the requirement.

Comment: Regarding §117.31(a)(15), one commenter stated that the door to a peritoneal dialysis room should be lockable.

Response: The department recognizes the need to control access to the peritoneal dialysis room during an exchange, but is concerned with patient safety issues. A door lockable from the inside renders the room inaccessible in the event of an emergency. Other methods to control access such as posting signs can be utilized. The requirement was not changed.

Comment: Regarding §117.31(a)(18), one commenter asked how comfort is assured.

Response: Comfort can be assured through proper ventilation. The ventilation system should not depend on open unscreened windows or doors, and the assessment of patient satisfaction relating to comfort should be a routine part of the facility's quality management activities.

Comment: Regarding §117.31(a)(19), one commenter requested "grandfathering" this requirement.

Response: The department disagrees. The section only applies to those facilities completed, renovated or modified after September 1, 1996, not to facilities providing services prior to that date.

Comment: In §117.31(a)(20), one commenter stated that the reference to the National Fire Protection Association's standard applies to testing for conductive flooring and flammable anesthetics, and suggested this standard be deleted as it is not relevant to dialysis facilities.

Response: The department agrees and deleted the standard. Because the reference to NFPA was deleted, the department revised the next reference to NFPA 99 in §117.31(b)(4) to clarify the reference to the publication.

Comment: Regarding §117.31(d)(2), two commenters stated that facilities should have an emergency system such as a back-up power generator in case of power outages.

Response: The department disagrees that a back-up generator should be mandatory; although the rules do not preclude its use. The department has striven to mirror the federal Medicare Conditions of Participation which do not require emergency generators for dialysis units; such generators represent significant financial investment and maintenance. The department did not change the language.

Comment: Concerning §117.32(a), one commenter stated that the chairs in the dialysis unit are not comfortable: the arms are too narrow and the backs are too short for tall people; and when reclined, this patient's feet extend past the foot rest, putting pressure on his calves.

Response: The department understands the commenter's concern that the language in §117.32(a) does not address treatment chairs. The department believes that the commenter's concern may be addressed under §117.43(a)(1), which requires that each facility ensure each patient is treated with full recognition of the patient's individuality and personal needs.

Comment: Concerning §117.32(a), one commenter asked the department to require that equipment and supplies for all dialysis patients meet the highest standards of performance.

Response: The department agrees that all equipment and supplies should be free of defects and maintained in safe working condition and that the commenter's concern is reflected in the rule language in §117.32(a).

Comment: In §117.32(a), one commenter suggested the addition of a reference to the federal Food and Drug Administration's safe medical device act for the reporting of an injury or death related to a possibly defective medical device.

Response: The department agrees and has added the reference at §117.32(a)(5).

Comment: Regarding §117.32(a)(1), seven commenters recommended the mechanical technician be in the building at all times the facility is in operation.

Response: The department disagrees. There is a requirement for backup equipment to allow staff to replace malfunctioning equipment if the staff member responsible for repair is not on duty. The department did not add a requirement for constant presence of the mechanical technician.

Comment: Regarding §117.32(a)(2), one commenter wanted clarification of what constitutes a malfunction, asking if operator correctable alarm situations would be considered a malfunction.

Response: The department is aware that dialysis equipment includes multiple alarms to signal the need for monitoring or adjustment. An alarm does not constitute a malfunction; it demonstrates the equipment is functioning correctly.

Comment: Concerning §117.32(b), three commenters questioned the choice of 30-day maintenance in the absence of manufacturer's recommendations, suggesting that today's equipment requires less frequent maintenance. One of these commenters suggested language to include that equipment receive electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. Another commenter requested clarification on who would be responsible for the maintenance of dialysis equipment in a patient's home.

Response: The department agrees and has changed the language. Regarding the maintenance of the equipment, facility staff could provide this service, or the service could be contracted (e.g. to the equipment vendor).

Comment: Concerning §117.32(c), three commenters stated that this requirement was not necessary and would require facilities to purchase unneeded extra machines. One of the commenters suggested that patients could be rescheduled to a different shift if equipment was down. The other commenter

stated that some patients are always in the hospital and the machines reserved for these patients were available for backup.

Response: The department disagrees. The department previously was encouraged to require one backup for every six machines in use and believes that one backup machine per ten machines is a reasonable requirement to assure patients are treated as scheduled.

Comment: Regarding §117.32(d), one commenter suggested specifying certain equipment that would need to be appropriately sized, such as blood pressure cuffs, dialyzers, and blood tubing.

Response: The department agrees and added these items as examples of equipment that should be available in appropriate sizes for pediatric patients.

Comment: In §117.32(e), one commenter stated that the phone number given may not be correct.

Response: The department agrees and corrected the number.

Comment: Regarding §117.32(g), four commenters suggested the changing the rule to require an electrocardiograph (EKG) machine, defibrillator or automatic external defibrillator (AED). Three commenters requested that the requirement for a defibrillator or AED be deleted, stating that staff would need to be certified in advance life support to competently use a defibrillator, and that community emergency support services respond in only minutes. Another commenter stated each facility needs an EKG machine.

Response: The department agrees and deleted the requirement for a defibrillator or AED, and maintained the requirement for an EKG machine.

Comment: Regarding §117.32(g)(2), one commenter suggested listing pediatric equipment and supplies to include but not limited to appropriately sized blood pressure cuffs, airways, endotracheal tubes, AMBU bags, peritoneal dialysis catheters, hemodialysis catheters, dialyzers, blood lines, topical anesthetics, nomograms for blood pressures in children (male/female), and growth charts (male/female) to include frontal occipital circumferences in children below two years of age. Two commenters suggested changing the language of the rule to add "appropriate type and size equipment for this special population." Another commenter recommended facilities be equipped and have suitable equipment for pediatric advanced life support in the event of an emergency.

Response: The department agrees with the addition of "type and size" to the current language and has made the change. The specificity recommended by the first commenter is not necessary and was not added. Regarding the suggestion relating to pediatric advanced life support, the department disagrees with the commenter. The standard of practice in outpatient dialysis facilities is to provide basic life support and access local emergency medical services for immediate transfer to a hospital emergency room.

Comment: Concerning §117.32(h), one commenter requested that this standard apply only to central delivery systems for bicarbonate dialysate with glucose, as bicarbonate dialysate without glucose does not have problems with rapid bacterial growth.

Response: The department agrees with the commenter and added "glucose-containing" bicarbonate dialysate to the rule language.

Comment: Referring to §117.32(h), one commenter described a system where the bicarbonate dialysate is mixed in a large quantity, then dispensed into jugs for individual machines and questioned whether this would qualify as a central delivery system.

Response: The system described by the commenter does not qualify as a central delivery system. A central delivery system requires the mixed dialysate to be piped from a central location to each individual machine, where it is delivered directly into the machine's proportioning system.

Comment: Referring to §117.32(h), two commenters expressed concern that these requirements would "close down" a unit should the cultures be positive and asked that the requirement be changed to allow the system to be disinfected and recultured, but not taken out of service awaiting negative results.

Response: The department agrees and deleted the language requiring the results of the cultures to be known before the system may be restored to use.

Comment: Regarding §117.33, one commenter stated that Medicare standards are already required and are sufficient to protect patient safety and these additional regulations relating to water treatment and reuse are unnecessary if Medicare and American Association for the Advancement of Medical Instrumentation (AAMI) standards are referred to in the rules. The commenter stated that all facilities should be currently meeting the Medicare standards so no additional cost would be incurred. Another commenter suggested elimination of the detail and an amendment of the rule to read "all equipment shall be in compliance with AAMI standards."

Response: The department disagrees that the language requiring compliance with AAMI standards is not necessary, and has not changed the language.

Comment: Regarding §117.33(b)(6), one commenters expressed concern that the proposed language did not assure that at least one carbon tank is required.

Response: The department agrees that clarification was necessary and has amended the language to clearly specify when source water is from a private supply, and the water treatment system for dialysis shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

Comment: Regarding §117.33(b)(6), one commenter recommended that this language be altered to require two carbon tanks "in series."

Response: The department agrees and changed the language in §117.33(b)(6) and §117.33(b)(6)(C).

Comment: Regarding §117.33(b)(6), one commenter asked if this standard applies to hospital portable water treatment systems for acute patients.

Response: The statute and these rules apply only to the providers of outpatient ESRD services. They do not apply to acute hospital services for inpatients. The language was not changed to address the commenter's concern.

Comment: Concerning §117.33(b)(6)(C), one commenter recommended changing the language to require an empty carbon bed contact time of three minutes instead of the proposed five minutes, the inclusion of an iodine number, which relates to carbon absorption ability, and a range of mesh sizes for carbon particles used in carbon tanks.

Response: The department agrees in part. The AAMI standards recommend an empty bed contact time (EBCT) of three to five minutes. The rule language was amended to require an EBCT of a minimum of three minutes per tank or bank of tanks. The department does not believe it is necessary to include an iodine number. The language relating to mesh size does allow a range in that the size must be 30-mesh or smaller and was not changed.

Comment: Regarding §117.33(b)(6)(C), one commenter expressed support for the requirement that water from the testing port between tanks be tested for chlorine/chloramine level before each patient shift.

Response: The department agrees.

Comment: Regarding §117.33(b)(6)(C), one commenter stated that the wording needed to reflect that some facilities utilize more than two carbon tanks by changing it to read "tank/bank of tanks."

Response: The department agrees and changed the language to acknowledge that some facilities use more than two tanks.

Comment: Concerning §117.33(b)(6)(D), one commenter recommended that standards for chlorine and chloramine be changed to 0.5 parts per million (ppm) for chlorine and 0.1 ppm for chloramine to reflect the AAMI standards.

Response: The department agrees and has changed the wording. The department had proposed the lower standard of 0.1 ppm for both chlorine/chloramine with the view that facilities would be able to test for only total chlorine, use the accepted level for chloramine, and avoid conducting two tests. In response to this comment, and to maintain consistency with the AAMI standards, the department has added language to include AAMI recommended limits of 0.5 ppm for chlorine and 0.1 ppm for chloramine.

Comment: Regarding §117.33(b)(6)(D), one commenter suggested that wording of this section utilize the terms "workhorse" and "polisher" instead of "first tank" and "second tank" to better describe the purpose of the two tanks. The commenter also requested that the meanings of these terms be added to the definitions. The commenter indicated that this terminology would address situations where a bank of tanks was used in contrast to single tanks placed in series.

Response: The department agrees that the wording should be changed and has amended the language, but did not use the terms "workhorse" and "polisher" as suggested by the commenter.

Comment: Regarding §117.33(b)(7), one commenter asked that the language be deleted as the purpose of the water softener is to remove hardness from the water and has no direct patient effect.

Response: The department disagrees and has not changed the language. In addition to protecting the reverse osmosis (RO) membrane from scaling, the water softener also serves to protect the patient from hard water minerals such as calcium and magnesium. The AAMI standard maximum contaminant level for calcium is 2.0 ppm before the risk of "hard water syndrome" occurs. If an RO system working at 98% rejection is being fed water that is 10 grains hard, then 3.4 ppm of calcium will be passed to the patient. The treatment system's water softener(s) is fitted with a timer(s) to tell the system to regenerate the softener with brine when the resin is exhausted. The purpose of the language is to assure that regeneration of the softener(s) would not occur during treatment time exposing the downstream water to an excessive sodium load.

Comment: With regard to §117.33(b)(10), one commenter asked if visual and audible alarms are located in the water treatment room which is adjacent to the hospital dialysis treatment area, then is it acceptable for audible alarms to be heard in the dialysis treatment area. Another commenter asked if the rules for audible and visual alarms for the water treatment system which would be able to be heard and seen in the treatment room applied to home hemodialysis patients.

Response: The location of the alarms is not specified, but they must be heard and seen in the dialysis treatment area. The commenter referenced a hospital dialysis treatment area; these rules would only apply to a hospital facility that provides outpatient dialysis. Home water treatment systems for hemodialysis should be guarded by alarms and testing to ensure safe water is available at the start of each treatment. Audible and visual alarms for water systems for use by multiple patient stations would not be expected in a home setting. The language was not changed.

Comment: Regarding §117.33(b)(13), one commenter recommended keeping the proposed language, one commenter stated that water at each station should be tested twice a year rather than quarterly, and a third commenter stated that each station did not need to be tested as tests done at the beginning, the end and in the middle of the water distribution system would show bacterial growth anywhere in the system. A fourth commenter suggested that individual stations be tested only when the results of testing sites at the beginning and end of the system were not within AAMI standards.

Response: The department agrees with the commenters and changed the language to require routine testing of fewer sites, with a greater number of sites for testing required if results of testing are not within AAMI standards.

Comment: Concerning §117.33(b)(14), one commenter supported this standard.

Response: The department acknowledges the commenter's support.

Comment: In regard to §117.33(b)(16), one commenter asked what documentation would need to be maintained on file by the facility if all repair was done by a water treatment vendor. Another commenter questioned what would qualify as education or experience.

Response: The contract with the water treatment vendor should include language similar to the rule language in order to assure

that the vendor's employees were qualified by education or experience, and that the vendor would maintain supporting documentation, and supply the documentation upon the dialysis facility's request. Education could include college or technical institute courses in biomedical technology and courses offered by water treatment companies. Experience could be evidence of progressive responsibilities for water treatment systems for dialysis. The department changed the language to cross reference §117.44(f) relating to staff responsible for the water treatment system.

Comment: In regard to §117.33(c), one commenter stated the facility's reuse program should be an intense, extended program including strict testing with a mandatory quality assurance program.

Response: The department agrees and believes the rule language regarding reuse is sufficient to assure a facility's reuse program provides safe and effective reprocessed dialyzers. The language was not changed based upon the commenter's statement.

Comment: In regard to §117.33(c), one commenter recommended that decisions concerning reuse of dialyzers be left to the prescribing physicians, rather than patients. Two other commenters stated they should have the right to refuse reuse.

Response: The department agrees that decisions regarding reuse should be made by the prescribing physician, but also believes that patients should be able to participate in this process by being provided information about the reuse practices at the facility. The language in the rules reflects the department's goal to promote patient-physician communication regarding reuse; the language was not changed except as noted in the response to the comment on §117.33(c)(8).

Comment: Regarding §117.33(c)(3), one commenter supported prohibiting reuse of any blood lines, believing that the risk of contamination is too great. Another commenter stated that he knew of no such situation where arterial lines were labeled for reuse.

Response: The department disagrees that reuse of blood lines if allowed by federal law and in accordance with the manufacturer's recommendation should not be practiced. Further, the rule language mirrors the HCFA requirement for reuse of arterial lines. There are currently two lines on the market labeled in a way to allow reuse; the actual label includes language guaranteeing sterility for first use only. The department believes the language is sufficiently restrictive to protect patient welfare and did not amend the rule allowing reuse of blood lines under certain criteria. However, the department agrees that the language should be clarified and has amended it for that purpose.

Comment: Regarding §117.33(c)(4), two commenters recommended substituting "check valve" for "device."

Response: The department agrees and made the change.

Comment: Regarding §117.33(c)(6) and (8), one commenter expressed support for the rule, adding that at each treatment, the patient needs to be told which reuse number is on the dialyzer as the written number is often hard to find and see on the dialyzer. One commenter supported giving the patient information concerning reuse practices, an ongoing opportunity to inspect the reuse area and have questions answered, and requiring informed consent, but believed that posting the dialyzer reuse criteria may negatively impact patient trust and comfort, and informing patients of the number of reuses only irritates patients. This commenter stated that patient's reactions are sometimes based on unfounded fears and to constantly bring these to the forefront is not medically sound. Another commenter recommended reuse information be given to patients and that posting such information was not necessary.

Response: The department disagrees that apprehension about patients' reactions to information regarding their care is justifiable reason not to provide the information. Patients who are actively involved in their care and treatment fare better than patients who are passive recipients of care. Therefore, the department has retained the requirements for making reuse information available to patients, and deleted the requirement at §117.43(a)(9) that the patient be told the number of times a dialyzer was reused.

Comment: Regarding §117.33(c)(7), one commenter stated that the wording, "consider and address the health and safety of patients sensitive to disinfectant solutions residuals" is too vague. A second respondent commented all patients would be sensitive to residual solutions, and requested clarification of this rule language.

Response: The department disagrees that additional clarification is necessary. Some patients are known to have sensitivity reactions to minute amounts of disinfectant which remain in the potting compounds even after the dialyzer tests negative for disinfectant. Facilities will need to be watchful for symptoms of such sensitivity and take action to diminish the potential for such occurrences (i.e., consider a different disinfectant for that patient, extra rinsing of that patient's dialyzer, or not reprocessing that patient's dialyzer and provide a new one).

Comment: Regarding §117.33(c)(8), one commenter deleting the language relating to an inspection conducted by the patient of the reuse area. A separate commenter suggested that patients were not trained or qualified to inspect the reuse area.

Response: The department agrees that the term "inspect" is not appropriate and changed the language to "tour the reuse area."

Comment: Regarding §117.33(d), one commenter expressed support for requiring the use of automated reuse equipment when central reprocessing of dialyzers is performed, adding that the automation standardizes reuse outcomes which can lead to good patient outcomes.

Response: The department agrees and appreciates the support. The language was amended by changing the word "offsite" to "centralized" to recognize that reprocessing may be done in a facility for another facility(ies).

Comment: Regarding §117.33(d)(1), three commenters asked that semi-automated and manual systems be allowed for use in centralized reprocessing, with one of these commenters asking what is better about automated reprocessing and another of these commenters stating they believed that manual reprocessing is much more reliable.

Response: The department disagrees that manual reprocessing is more reliable than automated reprocessing. Centralized reprocessing, often done at a location off-site from the facility, is not addressed by AAMI or by the Medicare Conditions of Coverage. Surveyors who have reviewed facilities using manual reprocessing have observed that reuse technicians tend to make adaptations and "short-cut" facility procedures as they perform these repetitive tasks. Use of automated equipment prevents such practices, providing a more standard reprocessing procedure. While centralized reprocessing allows greater quality control by reducing the number of staff involved in the process, also resulting in cost savings, centralized reprocessing centers are not readily accessible for monitoring by the management of each dialysis facility sending dialyzers to the center. To ensure patient safety, the department retained the requirement for automated equipment if reprocessing is done at a central location off-site from the facility.

Comment: Regarding §117.34(a), one respondent commented that infection control must be stringent.

Response: The department agrees with the commenter and believes the rule language is sufficiently stringent with minor changes made to §117.34(a)(1)(B)(i) relating to the accessibility of hand washing sinks and §117.34(a)(3) relating to the smoking policy.

Comment: In regard to §117.34(a)(1)(B), one commenter stated that a requirement to wash hands before and after patient contact in which there is a potential exposure to blood should be adequate and the mention of body fluids and the language in clauses (i)-(iii) is not necessary.

Response: The department disagrees that the language in §117.43(a)(1)(B)(i)-(iii) is not necessary. Staff may also be exposed to body fluids (e.g., sputum, saliva, and vomitus); such exposure would require hand washing before contact with another patient. The language in clauses (i)-(iii) improves infection control capabilities.

Comment: Regarding §117.34(a)(1)(B)(i), one commenter asked if this standard applied to existing facilities.

Response: The language in §117.34(a)(1)(B)(i) applies to all dialysis facilities. The language has been amended to remove the specific ratio of sinks in response to other comments.

Comment: Regarding §117.34(a)(1)(B)(i), two commenters stated one sink to six stations is excessive, but one sink to eight stations would be plausible. Five commenters recommended that the ratio of sinks to stations should be deleted, and that the language should be changed to require sinks be easily available and in close proximity to the stations served. An additional commenter suggested that the accessibility and number of sinks be addressed in interpretive guidelines.

Response: The department agrees and deleted this ratio for sinks, adding language that requires that hand washing sinks shall be readily accessible in each patient care area.

Comment: Regarding §117.34(a)(1)(B)(i), one commenter suggested that guidelines be set for availability of "dirty" sinks, and recommended one for every 12 stations.

Response: The department disagrees that ratios for "dirty" sinks should be included. Each facility will need to review the practices individually and designate "dirty" and "clean" areas and sinks. The rule language was amended to eliminate a ratio for sinks altogether.

Comment: Concerning §117.34(a)(1)(B)(ii), one commenter stated that the use of hands-free valves causes great increase in the cost and space requirement of sinks, and that it implies that something more than simple hand washing is to take place after patient contact. Another commenter requested "grandfathering" of this requirement.

Response: The department disagrees that the use of hands-free valves is not necessary in an area where blood contamination is prevalent and that basic sanitary and hygienic practices such as preventing cross-contamination through hands-free lavatory fixtures should be grandfathered. During the course of providing dialysis treatment, patient care staff's hands are routinely exposed to blood when access needles are placed and removed. The rationale for "hands-free" operation is to prevent contamination of the handles by hands soiled with blood; therefore, the department has not changed the language.

Comment: Regarding §117.34(a)(1)(B)(ii), one commenter stated that hot air dryers should not be advocated for the same reasons as fans are not recommended (because of the downward draft of hand dryers could cause contaminants on the floor to become airborne).

Response: The department disagrees that the use of hot-air dryers should be prohibited as the use of such dryers is rare if existent. The language was not changed.

Comment: With regard to §117.34(a)(1)(C), two commenters questioned whether patients were to be protected from exposure to their own body fluids.

Response: The intent of the rule is to prevent a patient's hands from being contaminated with blood which is then transferred to surfaces in the dialysis unit and the community. Providing gloves to patients and family members who hold pressure on needle sites offers protection to the family member and the environment, and presents an opportunity for teaching patients and family members about infection control.

Comment: With regard to §117.34(a)(1)(C), one commenter stated that patients should be educated on basic sanitary and aseptic techniques and that if a glove is dropped on the floor it should not be picked up and used.

Response: The department agrees and believes the requirement as written will encourage the staff of dialysis facilities to educate patients on aseptic techniques and their importance. The language was not changed.

Comment: Concerning §117.34(a)(2)(B), one commenter stated infection rates must be monitored closely. A second commenter asked what type of infections are to be identified and tracked.

Response: The intent of this standard is to require close monitoring of the incidence of any infection in dialysis patients. The monitoring process should include identification of community acquired vs. nosocomial infections, and review for any evidence of trends or patterns of infection. The facility's quality assurance program must review this activity and the language was changed to make this clear.

Comment: Regarding §117.34(a)(3)(A), one commenter stated that this standard was extraneous to the more important issues within this document, and that rules with minimal impact on patient health and safety, quality of life or which are of low prevalence in the renal community should be kept to a minimum. Another commenter suggested the wording be changed to "A facility shall establish, implement, and enforce a smoking policy." A third commenter asked for the right to provide a separate area for smokers and protested the requirement to post signs, as they detract from the comfortable aesthetically pleasing environment the commenter's facility was trying to create.

Response: The department agrees that extraneous rules should be eliminated from the document, but believes that passive exposure to second-hand smoke has an impact on patient health and safety and this issue should be addressed in these rules. The language was amended as suggested by the second commenter, and reorganized by deleting subparagraphs (A)-(C).

Comment: With regard to §117.34(b)(1)(A)(ii), one commenter noted that the word "covered" should be "coved." Four commenters questioned if this language would require a seamless or sheet vinyl floor, rather than allowing the continued practice of using tile squares.

Response: The department did not intend to require a seamless or sheet vinyl floor and has deleted the word "covered" and amended the language to specify that the wall bases be tightly sealed to the floor and the wall. The intent of the rule is to prevent the accumulation of dirt and debris between floor tiles, the baseboard and the wall.

Comment: Concerning §117.34(b)(1)(A)(vi), one commenter stated that ceiling tiles stained with blood should be replaced immediately.

Response: The department agrees, but recognizes that it may be possible to clean some stains on some types of ceiling tiles rather than requiring the tile be replaced. No change was made.

Comment: Regarding §117.34(b)(1)(B)(ii), one commenter requested a change of the language to "If a solution of chlorine bleach is used, the solution should be at least 1 to 100 sodium hypochlorite and the surface to be treated must be compatible to this type of chemical treatment." Ten other commenters suggested the bleach solution strength might be a mistake, as their facilities commonly use a 1:100 solution, which one of these commenters stated kills the acquired immune deficiency syndrome (AIDS) and hepatitis viruses on contact. An additional commenter stated that the Centers for Disease Control recommends 0.5% sodium hypochlorite, and that 1:10 solutions destroys the outer covering of dialysis machines and clouds the screens on the machine computers.

Response: The department agrees that the solution strength was too great and has changed the solution strength to 1:100.

Comment: With regard to §117.34(b)(2)(B), one commenter asked that clarification be provided for the requirements for home patients, referencing the AAMI requirements which indicate the dialysate sample testing requirements for home patients can be less often. The commenter stated that their patients initially submit three monthly samples, and if these are okay, the frequency changes to quarterly.

Response: The department agrees and added language to clarify the requirements for cultures for home patients' machines which mirrors the commenter's suggestion.

Comment: With regard to §117.34(b)(2)(B), one commenter suggested to have dialysate samples from monthly cultures come from all dialysis machines rather than from a random selection as random sampling is more consistent with research than with quality assurance or continuous quality improvement methods.

Response: These are intended to be minimum standards. Each facility will need to evaluate their current practices and only make changes to practice when the standards in these rules are higher than the facility's current practice. Facilities which have implemented continuous quality improvement (CQI) programs which include monthly cultures from all dialysis machines are practicing above this minimum of random cultures. The rule was not changed to require all machines be cultured.

Comment: Regarding §117.34(b)(2)(C), one commenter stated it would be good for a patient to have their own blood pressure cuff. Two commenters stated that cleaning blood pressure cuffs between patients or patient shifts would not allow time for the cuff to dry before using again. These commenters suggested that if blood pressure cuffs are contaminated with blood, the cuff should be removed from service, disinfected and allowed to dry prior to returning the cuff to service, and that chair side stools should be treated as any other surface would be (cleaned immediately if contaminated).

Response: The department agrees on both issues, added language to describe the cleaning of blood pressure cuffs and deleted chair-side stools from the wording.

Comment: Regarding §117.34(d)(2)(B)(i) and §117.34(d)(2)(C)(iv), one commenter expressed concern about the proposed language relating to the treatment of hepatitis B positive patients, citing that the rule language contradicts itself because one section of the rules requires a facility to know the status a month before a patient comes in by screening the patient, and another section requires "and/or." The commenter stated that the rules should require testing before the patient is admitted, so that a facility will know whether to separate the patient if positive for hepatitis B. A second commenter stated that it was not appropriate to accept any patient, in any dialysis center, without a demonstrated positive or negative hepatitis B status and that the patient should not be allowed to dialyze in a facility unless the hepatitis B status is known. The commenter objected to putting a patient with unknown status in the isolation area with 17 hepatitis B positive patients, then finding out that the patient is negative, a practice which will definitely result in that patient's conversion to positive status. Five other commenters stated that this standard should require that a patient's hepatitis status must be known before the patient is admitted for treatment.

Response: The department agrees in part. In response to a comment that 50% of the patients admitted to one facility have an unknown hepatitis status at admission and their lab had an approximate 10-day turn around on results, the

department asked the Network staff to do a telephone survey of several more "remote" facilities to determine whether this was a common occurrence. These facilities reported having to admit patients before the hepatitis status was known, with an average lab turn around time of three days. While the department would prefer that each patient's hepatitis B surface antigen (HBsAg) status be known before admission, all Texas communities do not have access to a laboratory which can provide immediate turnaround of test results for HBsAg. The requirements at §117.34(d)(2)(C)(iv) have been amended to require that patients with an unknown hepatitis B status be segregated from both known positive and negative patients, and the status be determined within three days of admission.

Comment: Regarding §117.34(d)(2), one commenter stated that while concerns regarding the care of hepatitis B positive patients are important, the provision of care for patients with hepatitis C, human immunodeficiency virus (HIV), and vancomycin resistant enterococcus was a bigger question.

Response: The department agrees that control of cross contamination and prevention of infection is critical in dialysis facilities and addressed the importance of prevention of all communicable diseases in §117.34(b)(1) in the rules.

Comment: Regarding §117.34(d)(2)(C), one commenter stated the isolation requirements for hepatitis B are excessive and not warranted with the use of universal precautions, current serologic testing and immunization programs.

Response: The department disagrees. The requirements were based upon the recommendations of the Centers for Disease Control which were re-published on April 12, 1996. The department did change the proposed wording in §117.34(d)(2)(C)(iv) to address comments that patients whose test results are not known should not be dialyzed with known positive patients; deleted the term "terminally cleaned" from the language in §117.34(d)(2)(C)(iii) and (iv)(II); and added a new subclause (III) to §117.34(d)(2)(C)(iv) to require a facility to obtain HBsAg status results of a patient no later than three days after the patient's admission.

Comment: Regarding §117.34(d)(2)(C)(i), one commenter recommended changing the language related to sanitary and hygienic conditions for the provision of services to hepatitis B patients to state "adequate provisions for hand washing should be available" rather than the requirement for the separate sink available in any designated area for hepatitis B positive patient treatments. The commenter also suggested that each sink should be located in close proximity to the station served.

Response: The department does not agree. Separate hand washing facilities for use by staff caring for hepatitis B positive patients are needed to reduce the chances of cross contamination to negative patients. The language in §117.43(d)(2)(c)(i) was not changed.

Comment: Regarding §117.34(d)(2)(C)(i), one commenter stated that hepatitis B patients need to be in a separate room.

Response: The department disagrees as this requirement is meant to direct the isolation requirements for current facilities. New facilities or facilities which add or modify space for HBsAg positive patients are required by §117.31(a)(6) to provide a separate room for these patients. Of the 165 current facilities which responded to a staffing survey conducted by the department, only eight of the 62 facilities which dialyze HBsAg positive patients stated they do not utilize a separate room for these patients. The language was not changed.

Comment: Regarding §117.34(d)(2)(C)(i), four commenters suggested the addition of the language "separated by a physical barrier" after "segregated treatment area."

Response: The department disagrees. The department believes that "segregated treatment area" sufficiently conveys the requirement for separation of HBsAg positive patients from HBsAg negative patients. This minimum standard could be met by the use of distance in space or by physical barriers, with the facility having the flexibility to make that choice. The language was not changed.

Comment: Regarding §117.34(d)(2)(C)(i), five commenters asked that there be access to a hand washing sink, rather than the requirement that the hand washing sink be included in the segregated area.

Response: The department disagrees; this requirement is meant to assure that the patient care staff for the hepatitis positive patient(s) will be able to wash blood contaminated hands immediately and without possibly contaminating the general treatment area. The language was retained.

Comment: Regarding §117.34(e)(2)(B), one commenter questioned the need to screen patients for tuberculosis on admission to a facility, stating that patients are frequently anergic and will show little if any response to such testing.

Response: The department agrees and has deleted the requirement for screening for tuberculosis on admission. The remaining requirement would apply, if indicated, to patients when admitted.

Comment: Three commenters noted that §117.41 does not include a cross reference to the requirement at §117.34(a)(2)(B) regarding the inclusion of infection identification and tracking through the facility's quality assurance program.

Response: The department agrees and has added the language at §117.41(b).

Comment: Regarding §117.41, one commenter indicated that criteria and standards are needed before outcomes are reviewed.

Response: The department agrees and intends to observe for the development, validation, and acceptance of outcome measures by the renal community and will revisit these rules to incorporate the use of outcomes as criteria are identified. The rule language was not changed to specify quality assurance criteria.

Comment: Two commenters supported the requirements of §117.41, with one stating that these requirements should certainly be enforced.

Response: The department acknowledges the support.

Comment: Five commenters suggested the use of "continuous quality improvement (CQI)" instead of quality assurance (QA)" in §117.41.

Response: The Health and Safety Code, Chapter 251 requires the department to develop rule addressing quality assurance activities; therefore, the department has predominantly used the term "quality assurance." The department agrees that more current CQI processes should be mentioned and has done so in §117.41(a) which requires each facility's quality assurance program be based on the May 8, 1996, edition of the Network Criteria and Standards for quality management. The department has also amended §117.41(c) and (d), using the term "quality management" when referring to such meetings or activities.

Comment: Regarding §117.41, one commenter asked the department to denote who the "core" members are, and recommended these members include the medical director, supervising nurse, administrator, and director of technical services.

Response: The department agrees. The term "core staff members" is already defined in §117.2 relating to definitions. The individuals recommended by the commenter, plus the dietitian and social worker, are core staff members by definition. The language was not changed.

Comment: Regarding §117.41, one commenter suggested the department specify quality assurance criteria for peritoneal dialysis and recommended to include a time line of complications, infections, organisms grown, administration of antibiotics, and system and tube changes. The commenter stated that a peritoneal equilibration test (PET) or fast PET should be completed during the first 30 days of home dialysis, and per week creatinine clearances and KT/V should be done quarterly. The commenter concluded that the training nurse should provide and document continuing education for patients regarding new advances as well as correcting problems found in quality assurance review.

Response: The department appreciates the information, but believes that the facility should use the criteria and standards published by the Network as described in §117.41(a) to develop programs specific to the services provided at that facility. The department does not believe that the specificity recommended is required in the rules at this time.

Comment: Regarding §117.41, one commenter supported the requirement of quality assurance activities within the facility, saying these activities are designed to serve as a system to assess, monitor, improve and evaluate critical aspects of care on the facility level, and provide a mechanism to improve patient outcomes by defining what the best outcome should be, monitoring to see if that outcome is achieved, and if not, why and what can be done to achieve it. The commenter stated that a successful quality assurance program answers the critical questions of what is happening, why it is happening, and what can be done to change or improve the outcome, and the answer to this last question is implemented through a plan, then evaluated to determine if improvement was made and if the desired outcomes were achieved.

Response: The department agrees with the commenter and has maintained the requirements at §117.41(a) through (f) with the amendments described in this preamble.

Comment: Regarding §117.41(a), one commenter stated that on May 8, 1996, the Network had revised their criteria and standards for quality assurance referenced in the rule.

Response: The department appreciates the notification and has amended the language to reference the revised document and date of revision.

Comment: Regarding §117.41(b), one commenter suggested that close monitoring of infection rates be included.

Response: The department agrees that infection rates should be monitored and has added wording relating to this activity in §117.41(b) and a cross reference to §117.41(b) at §117.34(a)(2)(B).

Comment: Regarding §117.41(c) and §117.41(d), one commenter suggested the terms "quality assurance" should be changed to "quality management" to reflect the revised Network criteria and standards mentioned in §117.41(a).

Response: The department agrees and has changed the wording.

Comment: Regarding §117.41(d), one commenter suggested that although monthly staff meetings are ideal, quarterly staff meetings are sufficient to monitor quality assurance activities.

Response: The department does not agree. Quality assurance programs are intended to be dynamic, constantly changing to continuously evaluate and seek ways to improve the care delivered. Quarterly meetings would not provide the continuity or impetus to assure that this process of continuous improvement was promoted. The department has retained the requirement for monthly quality management meetings to review quality assurance issues and for consistency with the Network Quality Management Criteria and Standards which also require monthly quality committee meetings.

Comment: Regarding proposed §117.41(e), one commenter stated that incidents relating to death and serious injury should be reported timely and other incidents should be documented and available for review at the time of survey. The commenter concluded that the requirement as proposed would impose an undue administrative burden for lesser incidents (e.g. blood loss greater than 100 cubic centimeters and transfusion reaction). Two other commenters asked the department to amend two portions of proposed §117.41(e), adding that there can be many reasons for a blood loss greater than 100 cubic centimeters such as clotted dialyzers and agitated patients pulling out needles; and that one working day for notification is an unrealistic amount of time. The commenters recommended changing the reportable incidents to "any blood loss large enough to require transfusion," hospitalization, or death of patient, and allowing facilities one week to report.

Response: The department agrees in part and has deleted a portion of the language in §117.41(e) and added a new §117.41(f) which requires reporting within three days accidents or incidents resulting in death or hospitalization of a patient, conversion of staff or a patient to HBsAg positive status, or fire.

Comment: One commenter thought that the "director" in proposed §117.41(e) was the commissioner of health, that reporting to him would be too cumbersome, and recommended that the reports be limited to medically unjustifiable deaths. Nine

other commenters requested clarification of the identity of the "director" who is to receive the reports required by proposed §117.41(e).

Response: The "director" referred to in renumbered §117.41(f) is the director of the Health Facility Licensing Division of the department and is defined in §117.2. As previously noted, the department amended the language in §117.41(e) and added new §117.41(f) to list a reduced number of the types of incidents requiring reporting.

Comment: Regarding §117.41(e), one commenter recommended deleting the requirement to fax reports to the department of accidents or incidents which resulted in serious injury, death or hospitalization, stating the result would be a "blizzard of faxes" in the department offices. Seven other commenters asked if the requirements were not too excessive, and questioned whether the department would be able to follow up on all the problems to be reported and give immediate attention without any additional staff.

Response: The department agrees and has amended the language, adding a new §117.41(f) describing a more limited list of occurrences to be reported.

Comment: Regarding §117.41(e), 10 commenters suggested that the reporting period be extended to allow reports be sent three to five days after the occurrence of an incident. Another commenter stated the requirement in §117.41(e) is unreasonable because facilities have internal methods of monitoring and addressing adverse occurrences, that a 100 cubic centimeter blood loss in not uncommon if a system clots, there is usually not an adverse outcome, and that it was unclear whether the blood loss would have to be reported only if there is an adverse outcome. Another commenter suggested that §117.41(e) include pediatric parameters for blood loss which would be equal to or greater than 5.0% of blood volume to the list of reportable incidents.

Response: The department agrees that the reporting period specified at proposed §117.41(e) should be longer and amended the language in §117.41(e) and added new §117.41(f), reducing the list of occurrences that must be reported, eliminating a blood loss as a reportable event and allowing three days in which to report.

Comment: Regarding §117.41(e), one commenter stated that the language "shall be reported by facsimile" should read "shall be reported to the director within one working day," leaving the method of communication to the individual facility.

Response: The department agrees and has deleted the specification related to the method of reporting in §117.41(e), and added less specific language in new §117.41(f).

Comment: One commenter protested the requirement at §117.41(e), stating that the department would not have the manpower to respond to these reports, and the response would be after the needed action had been taken. The commenter suggested it would be more appropriate for such occurrences to be recorded within the dialysis facility, picked up by the facility's quality assurance system, and available for review at the yearly relicensing.

Response: The department disagrees that the reporting of certain incidents is not appropriate. In response to this and other comments, the department has reconsidered the events to be reported and has significantly reduced the list. Review of these reports, particularly when trends or multiple occurrences are identified, will assist the department in determining if a particular facility should be monitored more closely. The changes relating to this issue are to §117.41(e) and include the addition of §117.41(f).

Comment: One commenter recommended that §117.42(a) include an indicator of patient satisfaction with provider care. Two other commenters recommended that the indicators include a "quality of life" indicator.

Response: The department agrees in principle. The list of indicators in §117.42(a)(1)-(5) includes data which the department may request from a facility as part of the facility's annual report. Indicators will be added and changed in the future, as outcomes indicative of the provision of quality care are defined, validated, and accepted by the renal community. The rule was not changed.

Comment: One commenter stated the Network currently conducts data analysis for an annual report required by HCFA and asked if the requirements of §117.42 would result in the department duplicating what the Network is already doing.

Response: The department will contract with the Network to assist the department in accomplishing the work described in §117.42 and to avoid duplicate effort by either the department or the facilities. The language was not changed.

Comment: Regarding §117.42, one commenter asked when the annual report will be due to the department, if the facilities will receive this form from the department, and if the annual report will be part of the application for the initial temporary license.

Response: The annual report will not be part of the initial application packet as the submittal of the report is a requirement for the renewal of an annual license. The department will contract with the Network to assist in this work, and the intent is to incorporate the request for this report into the current process used to collect the data required by HCFA annually. The contents of the first report to be submitted by existing facilities in 1997 will most likely be limited to two indicators. This information will be presented at workshops for facilities to be held in August 1996.

Comment: One commenter suggested adding a new paragraph (6) to §117.42(a) to address access survival, strengthen quality assurance programs and make sure access sites are properly cared for.

Response: The department recognizes the importance of monitoring access complications, and may include the access issue as an indicator in the future as indicators are added and changed through the definition, validation, and acceptance of outcomes indicative of the provision of quality care by the renal community. The department did not change the language.

Comment: One commenter expressed concern that implementation of the requirements at §117.42 would be acceptable only if the data are compared to statewide and national data with long term trends, and if control charts developed according to

the methods of Deming or Joiner, are used to compare the data. The commenter expressed concern that the department would be usurping the authority of and tasks assigned to the Network by the federal government. The commenter stated there was no objection to the Network MRB advising the department about facilities which are seriously "out-of-line" and in which corrective action plans have been requested by the MRB. The commenter expressed further concerns about placing the review of quality of care under the State of Texas, and stated that the department is not qualified to render an opinion on the quality of services delivered to ESRD patients, that the department can interpret and enforce regulations, but it is not at all clear that regulations result in an increase in the quality of care. In addition, the commenter asserted that the adoption of the rules will undermine the authority of the MRB, which has worked diligently to improve care for Texas ESRD patients, conceptualizing that the providers wish to deliver good care with the MRB as an educational resource. The commenter concluded that if §117.42 is adopted, the focus of facilities will be on paperwork and deviances which is not how one improves the provision of care; improved care comes from an improved process, not from regulations.

Response: The department disagrees that the state regulatory process cannot serve a proactive role with the Network to improve care delivered to ESRD patients. The department has no intention to usurp the authority of the MRB. The Network staff and the MRB have been intimately involved in developing the statute and these rules. Language in the statute directs the department to require annual reporting by facilities of quality indicator data. The department and the MRB will be working together to develop indicators in conjunction with HCFA reporting requirements to prevent redundant requests. The department is developing a contract with the Network to assist the department in collecting, categorizing, and evaluating the annual report data. Network staff have indicated that the licensing program funding will enable the Network to extend its review, formerly limited to sample facilities, to all facilities in Texas.

Comment: Regarding §117.42(a)(5), one commenter requested a definition of a formula for the referenced hospitalization rate which may be calculated in different ways.

Response: The department understands the commenter's concern. The indicators listed are examples. Additional information will be provided to facilities regarding what method should be used to calculate the information should hospitalization rate be recommended by the Network MRB and selected by the department as an indicator on a future annual report.

Comment: Two commenters suggested that the language at §117.43(a) be revised to add "specific to its patient population," to ensure that the unique needs of pediatric patients are reflected in the facility's statement of patient rights.

Response: The department agrees and amended the language by adding "appropriate to the population served."

Comment: Regarding §117.43(a), one commenter suggested that patient rights and responsibilities be age-appropriate to include the pediatric population. Another commenter requested language be added to allow visitors during dialysis treatments.

Response: The department believes the change to "appropriate to the patient population served" will ensure rights and responsibilities are age-appropriate, and has made that change to §117.43(a). The department agrees that facilities should allow patients to have visitors during treatment, but believes the standard in §117.43(a)(1) is sufficient to assure that a facility allows reasonable access for visitors; therefore, no change was made to address the issue of visitors.

Comment: Regarding §117.43(a), one commenter stated that patient rights are very important and the patient should be able to make a suggestion or complaint without fear of reprisal from staff members.

Response: The department agrees and has addressed that patient right at §117.43(a)(14).

Comment: One commenter stated the requirement in §117.43(a) is exceptionally broad and asked why the dialysis facility and staff are responsible for total care, asking if some patients lack indoor plumbing how is the dialysis facility expected to correct the situation.

Response: The department refers the commenter to the Medicare Conditions for Coverage which specify very similar requirements. Regarding the patient without indoor plumbing, while the department would not expect the facility to be responsible for correcting that situation, the facility's social worker should have some referral sources for possible assistance. No change was made.

Comment: Concerning §117.43(a), one commenter stated that a glass of ice is never offered.

Response: The department acknowledges that some services such as being offered ice are desirable, but recognizes the multitude of restrictions which may prohibit the provision of such services. The department expects facility staff to respond to such requests from patients in a manner that explains the reasons some requests cannot be honored. No change was made.

Comment: Three commenters considered the language at §117.43(a)(1) to be vague, open for interpretation and therefore unenforceable. One of these commenters stated the language was prone to subjective interpretation; and another of the commenters stated that the standard would be impossible to objectively evaluate.

Response: The department disagrees. In enforcing Medicare standards for dialysis facilities as well as other licensed entities, the department has learned that patients and staff recognize when patients are not treated with respect and dignity. Surveyor observation of patient to staff interaction and review of information obtained via patient interview are important tools to establish compliance with this requirement. The department also reminds the commenter that this language is consistent with current HCFA requirements effective since 1976.

Comment: Regarding §117.43(a), one commenter alleged very little effort is made to encourage patients to go to home dialysis.

Response: The department acknowledges that every facility may not provide adequate information to allow patients to make an informed choice of treatment modality and believes that the language in §117.43(a)(6) addresses this issue.

Comment: Concerning §117.43(a), one commenter requested that physicians schedule their visit so family members can be present.

Response: The department agrees that family members should have access to talk with the physician, but believes this should be addressed on an individual basis as requested by the patient or family member.

Comment: Concerning §117.43(a)(1), one commenter asked what will be the outcome when the facility attempts to recognize one patient's individuality and personal needs but infringes on another patient's needs (e.g., a patient displays lewd or offensive behavior).

Response: Recognizing a patient's individuality does not mean acceptance of inappropriate behavior. The department expects the facility to require that each patient respect the staff and other patients, and that lewd offensive behavior would be prohibited. No change was made.

Comment: Two commenters protested the requirement at §117.43(a)(4) to have written materials available in Spanish in all facilities. Another commenter stated there is an expense in obtaining written materials in languages other than English, and that many of his patients are blind or illiterate. The commenter continued that the physician has the responsibility to communicate with the patients, and rules such as this only serve as catchalls for surveyors to use.

Response: While the department agrees the physician has a responsibility to communicate with the patients, there must be a method for communication by all staff members who deliver care to the patient. The department has amended the language to require written materials in any language only when there are four or more patients in a facility who read that language; the provision of other communication methods is expected for patients who are blind or illiterate.

Comment: Regarding §117.43(a)(4), one commenter stated that patient information can be provided by means other than written materials and the requirement to provide written materials in a variety of languages is not efficient.

Response: The department agrees that patient information can be provided in many different ways. This rule requires that patients be provided information in a manner to facilitate understanding. The provision of educational materials in the language a patient can read will facilitate his or her understanding, and the language was amended.

Comment: Regarding §117.43(a)(9), three commenters considered telling the patient the number of times his dialyzer had been reprocessed prior to each treatment unnecessary and undesirable as it would tend to make the patient uncomfortable.

Response: The department agrees and deleted that portion of the requirement at §117.43(a)(9).

Comment: Regarding §117.43(a)(9), one commenter suggested that the patient be told the number of reuses for his dialyzer at his request. Another commenter stated that patients should have a right to a new dialyzer at all times.

Response: The department agrees with the commenters that patients be given information on the number of times the dialyzer has been reused when requested and does not believe additional regulatory language is needed to assure that it would be provided if requested. The department disagrees that reuse should be prohibited. Reuse of hemodialyzers has been practiced since the 1970's, without evidence of adverse outcomes to patients. The department considered including a right for a patient to refuse reuse of a dialyzer, but decided against this because there is no evidence to support such a requirement and inclusion of such a requirement could be a financial disincentive to facilities to provide newer, more expensive dialyzers, depriving patients of the advantages of dialyzers that are more efficient and effective and which have better bio-compatibility.

Comment: Two commenters considered §117.43(a)(10) to be too vague and without meaning. One of these commenters asked for the meaning of "reasonable," and suggested that this was subjective and that this section should be deleted.

Response: The department disagrees. Compliance is measured by interviews of patients and review of records including notes by staff such as social workers which demonstrate efforts to meet a request or to assist the patient in understanding why his request could not be granted.

Comment: One commenter protested the requirement in §117.43(a)(11), stating that what is feasible and possible for the facility may not be perceived to be so by a patient or his family. This commenter expressed concerns about the legal liability of a facility should this standard be implemented, that this requirement would result in inefficient scheduling, and that there was no data to support that patient directed scheduling improves the quality of care. Two other commenters expressed concern that the requirement that hours of dialysis treatment be scheduled for patient convenience when feasible would place an undue financial burden on facilities, and result in legal liability to the facility if the hours were not convenient.

Response: The department disagrees and believes that the language in §117.43(a)(11) offers sufficient protection from frivolous suit by using the terms "whenever feasible or possible" in regard to the facility. The requirement does not relate to patient directed scheduling. Communication with patients and family would need to demonstrate that efforts were made to work with the patient's individual needs within the capability of the facility, with the facility staff maintaining responsibility for the final decisions about staffing. This area is one which mirrors the federal requirements for dialysis facilities.

Comment: Regarding §117.43(a)(11), one commenter asked if management provides facilities in small towns so that patients do not have to travel, could the rules recognize that those facilities may not have as much flexibility in scheduling for patients.

Response: The department agrees and believes that the language "whenever feasible or possible" recognizes these constraints. The language was not changed.

Comment: Two commenters noted that the language at §117.43(a)(12) does not address staff safety as a reason for patient transfer.

Response: The department acknowledges this oversight and has added "or staff members" to the language.

Comment: Regarding §117.43(a)(12), one commenter asked if this provision would interfere with a physician's right to terminate care with a patient.

Response: These rules apply to the provision of dialysis service by a dialysis facility, not to the physician's practice. The rule language was not changed except as noted in response to other comments.

Comment: Regarding §117.43(a)(12), one commenter asked what would happen if a facility transferred a patient for non-compliance or disciplinary reasons.

Response: The department agrees that patient behavior could be a cause for transfer and is covered by the language in §117.43(a)(12). For further clarification, the department has added "or staff members" to the text.

Comment: Regarding §117.43(a)(13), one commenter stated the staff in a dialysis facility should be able to resuscitate even in the face of advance directives and have the ambulance attendant take the advance directive to the hospital emergency room to allow the hospital staff to carry out the patient's wishes.

Response: The department does not agree. Although the laws allow resuscitation even if there is an advance directive, the facility staff should respect the patient's wishes regarding the level of care to be provided in the event of need for resuscitation. This rule would encourage staff and patient education regarding these issues and lead to increased comfort levels regarding such actions.

Comment: One commenter expressed appreciation for the requirement at §117.43(a)(14) which allows patients to complain without fear of reprisal or denial of services. The commenter continued that the department would have received many comments from patients or their families if they had been assured no action would be taken against them.

Response: The department agrees and has retained the language.

Comment: Regarding §117.43(a)(15), one commenter stated that posting these items was too cumbersome, and asked that a reference to materials available regarding reuse and patient rights be posted next to the license instead.

Response: The department disagrees. Information regarding reuse parameters and patient rights should not have to be requested by a patient or family member and neither subject requires extensive language to be posted. The language was not changed.

Comment: Regarding §117.43(a)(15), one commenter stated that the items detailed in §117.43 (a)(1)-(15) did not include clear patient responsibilities, yet this paragraph requires that patients be informed of the "responsibilities listed."

Response: The department agrees and has amended the language to require the facility to inform patients of their responsibilities, as established by the facility.

Comment: One commenter suggested that §117.43(b) contains a host of requirements that are beyond the capability of a dialysis facility to address given the limited financial resources and personnel.

Response: The department disagrees. The requirements specified in this section closely mirror the HCFA requirements which facilities have been expected to meet since 1976. Differences in this language and the current HCFA requirements are due to the revised HCFA requirements expected to be published this year. These differences are the requirements for treatment goals, and for interventions when goals are not attained. These requirements are in keeping with the continuous quality improvement methods reflected in the Network Criteria and Standards adopted May 8, 1996 by the Network MRB and referenced in §117.41(a).

Comment: Regarding §117.43(b)(2), one commenter expressed concern about creating estimated time tables for measurable and expected outcomes.

Response: The standard in §117.43(b) requires that the care plan process be useful, not paper compliance. This means that goals should be mutually agreed upon by the patient and interdisciplinary team, and that intervention be made when the treatment goals are not achieved. The language was amended to address the commenter's concern, eliminating the requirement for measurable and expected outcomes and estimated timetables, and adding a requirement for the inclusion of treatment goals.

Comment: Regarding §117.43(b)(3), one commenter stated that their medical director refuses to attend care plan meetings and said that the medical director believes that his monthly progress note dictation is sufficient.

Response: The requirement in §117.43(b)(3) is consistent with the Medicare Conditions of Coverage which require the medical director to participate in patient care planning, which must be completed by an interdisciplinary group to include the patient. These standards require the patient's primary physician to participate in the care planning sessions. Should the medical director fail to participate in care planning for his or her own patients, this failure would be cited by department survey staff as a licensure deficiency and would require a corrective action plan be completed by the facility. The language was retained.

Comment: Regarding §117.43(b)(3), one commenter asked how the term "evidence of coordination" will be interpreted, expressing concern that department survey staff may want phone logs and contracts to prove coordination was performed.

Response: The department expects that problems with other service providers which impact the provision of safe care will be prevented if possible or addressed should they occur. For example, it is expected that the clinical record of a nursing home resident demonstrate communication with the staff in the nursing home concerning food and fluid restrictions for this patient. If a patient describes problems in transportation to the surveyor, the record should demonstrate that staff are aware of the problem and an interview of the social worker should reflect actions taken to address the problem. There is no requirement relating to phone logs or contracts. The language was retained.

Comment: Regarding §117.43(b)(5), one commenter recommended monthly short term care meetings of the interdisciplinary team.

Response: The department disagrees and has retained the requirement at §117.43(b)(5) which allows the assessment of

an individual patient to determine the frequency of the care planning session.

Comment: Regarding §117.43(c)(2), one commenter asked why a dialysis center would need to access a community service, stating this should be a continuous quality improvement project for facilities which experience problems with their emergency medical service (EMS) provider. The commenter asked that this rule be omitted. Another commenter asked if dialing 911 would suffice to meet this rule, and asked for background for the rule.

Response: The department disagrees. The majority of outpatient dialysis facilities in Texas are free-standing rather than hospital based and use local EMS services for transport of critically ill patients to acute care hospitals. The plan is also necessary in the event of an emergency disaster. The department does not agree that dialing 911 would be equivalent to having a functional plan to access the community emergency medical services. There are areas in Texas which do not have "911" service. This requirement is intended to assure that facilities contact their local emergency medical services to determine such information as average response time, skill level of staff manning the mobile units, and equipment available in those units. This information would be used in developing the facility's plan for emergency medical care, which would also include how to access the emergency service. No change was made.

Comment: Regarding §117.43(c)(3), many commenters requested clarification of "personnel qualified to operate" and "administer emergency life support," asking if this meant advanced cardiac life support (ACLS) or basic cardiac life support (BCLS). The commenters believed that ACLS is unnecessary for dialysis facility staff due to the excellent EMS services in the Metroplex; suggested the department define "technical staff"; asked if staff with responsibilities for water and equipment only would be considered technical staff; opposed requiring staff be ACLS qualified, stating a cardiac arrest in a dialysis facility is a rare event, and the literature demonstrates that maintaining ACLS skills requires dealing with such problems on a day-to-day basis; suggested that nurses with ACLS certification in a dialysis facility are uncomfortable performing those skills because they use them so infrequently; recommended requiring both clinical and technical staff maintain current certification and competency in basic life support; and objected to the requirement as costly, unnecessary and difficult to maintain.

Response: The department agrees that this rule needs clarification and has amended the language to clearly require BCLS skills, while recognizing that not all dialysis facilities are located in metropolitan areas. The words "and technical" were deleted from the staff who needed to be certified in BCLS.

Comment: Regarding §117.43(c)(3), one commenter stated that if an RN is required in proposed §117.43(e)(2), the sentence referring to the RN presence in §117.43(c)(3) is superfluous.

Response: The department disagrees this requirement is superfluous but has changed the language in response to other comments.

Comment: Regarding §117.43(c)(3), one commenter stated they could not support the requirement for ACLS due to the requirements for time off to study for the course, to take the course, travel to the course, the expense, potential to fail the test, and need to start over. The commenter suggested the rules focus on skilled nursing assessment by an RN to identify patients who are too unstable to begin or continue dialysis on a given day, BCLS by all staff, and protocols/standing orders for basic emergency medications and activation of the local EMS system. Another commenter stated having an ACLS qualified nurse present at all times is hard to justify, stating it is more important to focus on prevention of a patient having any kind of emergency. The commenter suggested staff be BCLS qualified and facilities get paramedics in who do this frequently, as no one's skills can be up to standard if they are not used frequently. A third commenter stated that in an outpatient facility, the nurse's role should be to provide BCLS until "911" arrives. The commenter stated that physicians are seldom in the centers to provide oversight for intubation and defibrillation and more harm may come to the patient when staff has had little practice time in skills such as reading monitors or visualizing vocal cords for intubation.

Response: The department agrees and has clarified the language to assure the commenters that ACLS is not required.

Comment: Four commenters supported a requirement for ACLS certification in §117.43(c)(3).

Response: The department disagrees that ACLS should be mandated. The language was changed to reflect that BCLS is required.

Comment: Regarding §117.43(c)(3), two commenters asked that wording be added to this requirement to show that the staff maintain competency or demonstrate proficiency in BCLS.

Response: The department agrees and has added "and competency" following "maintain current certification."

Comment: Concerning §117.43(c)(3), 10 commenters asked that the language be amended to provide for the use of an LVN in lieu of an RN, when an RN was unavailable and as long as the facility provided written notification to the department.

Response: The department agrees in that there may not currently be a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas and has amended the language in §117.43(c)(3) to require a charge nurse, rather than an RN, qualified to provide BCLS be on site. A definition of "charge nurse" has been added to §l17.2, and a three-year phase-in period has been provided in §117.44(c)(3) to allow an LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. Facilities will still be required to have a full-time supervising RN under renumbered §117.43(e)(2).

Comment: Two commenters suggested that the language in §117.43(c)(3) was of concern because of the apparent assumption that ACLS would be required, since a defibrillator was required at §117.32(g)(1)(F). One of the two commenters suggested that only the last sentence of §117.43(c)(3) as it is currently written, remain in the final rules. One commenter considered the language in §117.43(c)(3) to be unclear whether ACLS certification of RNs is required. The commenter stated the frequency of patients coding in a facility is rare and the RN's skills are not regularly utilized. Even in rural areas a "911"

response can result in better patient outcome than possible with an RN whose ACLS skills are not routinely used. The commenter recommended deletion of any reference to RN ACLS certification.

Response: The department has clarified the language to specify BCLS is required and deleted the requirement for a defibrillator in §117.32(g)(1). In addition, the requirement for an RN with BCLS certification to be on site was replaced with a requirement for a charge nurse as defined in §117.2 with BCLS certification to be on site.

Comment: Regarding §117.43(c)(3), one commenter suggested that nurses and physicians should be current and certified in pediatric advanced life support.

Response: The department agrees in part. Staff who care for pediatric patients should be qualified to administer basic pediatric life support. The department believes that it is not necessary to add this language as the department expects facilities who admit pediatric patients to have staff qualified to care for these patients.

Comment: Regarding §117.43(c)(3), one commenter provided information about the attempted implementation of a requirement for ACLS in their dialysis facility. The commenter stated that three years ago, their facility adopted a policy that all RNs would become ACLS trained within one year, and only three of six were able to pass the test to complete the training because the testing is very complex and involves aspects of cardiac care that are rarely used in the routine care of the ESRD patient. The commenter added that its facility's EMS provider is located near the facility and has always had a good response time, and the physician's office is across the street from the facility. After reassessment of this policy, the commenter states the policy was omitted. The commenter supports the rule that all clinical staff (not mechanical technicians) maintain current CPR training.

Response: The department has clarified the language to clearly require BCLS certification and deleted the requirement for technical staff to be certified.

Comment: Regarding §117.43(c)(4), one commenter stated there is no need for this requirement as hospitals are required to provide emergency treatment whenever a patient is brought to the hospital. The commenter feels this is just an administrative burden which might be time consuming considering how fast hospitals change ownership.

Response: The department disagrees. The intent of the requirement is to assure a smooth safe transfer of patients to inpatient care. An agreement worked out ahead of time will help to assure this is accomplished and promotes continuity of care. No change was made.

Comment: Regarding §117.43(c)(5)(B), one commenter states that the 1-800 number published was not correct.

Response: The department agrees and apologizes for the error. The correct number is 1-800-344-3555 and has been placed in the rule.

Comment: Regarding §117.43(c)(5)(C), one commenter expressed never to have seen a fire in a dialysis facility and doubted that a fire would ever occur. The commenter believed that requiring fire drills in the midst of dialysis is to invite disaster, and to go through the motions without taking the patients off dialysis will do nothing but cause pandemonium, confusion, and laughter for the patients.

Response: The department agrees in part. During dialysis, a patient's mobility is restricted by the connection of the blood lines from their vascular access to the dialysis machine. Patients have told surveyors that they have worried about what would happen in a facility if there were a fire. The standard does not require patient treatments be interrupted, but that patients receive information and instruction regarding what actions would be taken in the event of a fire in the facility. The department has amended the language to eliminate the requirement for simulated evacuation and substituted discussion with patients, visitors, employees and staff about the evacuation plan.

Comment: Regarding §117.43(d)(3), one commenter stated that 30 days is too long to wait for a physician's countersignature, that most hospitals mandate a time limit of 24 hours, and that a dialysis patient may experience a number of problems within 30 days.

Response: The department agrees in part and has changed the time period for countersignature to 15 days.

Comment: Regarding §117.43(d)(3), one commenter expressed surprise that the physician can give a verbal order to change a medication over the phone to a nurse or other person without having to sign the order for 30 days, and questioned who would remember to sign the order.

Response: The department based this standard on draft language that physicians see each patient at least every 30 days. The countersignature requirement was changed to every 15 days which corresponds with the requirement for frequency of physician visits described in §117.43(j)(2)(C).

Comment: Regarding §117.43(d)(7), one commenter stated the practice in their facility since opening 19 years ago has been to have licensed staff prepare access needles, heparin, and xylocaine to initiate the dialysis treatment while other unlicensed and licensed staff perform duties such as prepare machines or check the water. The commenter believes this has been a safe and effective procedure and recommends that the licensed staff be able to prepare the medications and label the syringes as long as the staff who use them check the amounts in the syringes and compare with the patient's record prior to the initiation of treatment.

Response: The department does not agree this is a safe method of medication administration and questions whether the Board of Nurse Examiners would approve of the RN preparing medications for administration by an unlicensed person, since the Nurse Practice Act prohibits RN delegation of medication administration to unlicensed persons. The standard of practice in medication administration requires the individual prepare medications that they are to administer. However, in accordance with the Medical Practice Act, the physician may delegate medication administration to unlicensed staff.

Comment: Regarding §117.43(d)(8), one commenter noted that medication administration by unlicensed staff was cross-referenced to §117.62(b), but not to §117.62(f); and that it would be more appropriate to cross-reference §117.63(b), (c) and (e) instead of §117.63(d) in the rule.

Response: The department agrees and has amended the cross references in §117.43(d)(8) as suggested by the commenter.

Comment: Regarding §117.43(e), 36 commenters expressed strong support for the rules, especially those pertaining to the supervising nurse, the presence of an RN during treatment and the staffing of licensed personnel. The commenters believed that these rules ensure qualified nursing staff, adequate staffing and that quality nursing services are provided to dialysis patients.

Response: The department agrees, but has changed the language in §117.43(e)(4), (5), (7), and (10) in response to other comments.

Comment: Regarding §117.43(e), one commenter reported that the American Nephrology Nurses' Association (ANNA) and the Board of Nurse Examiners prohibit the delegation of patient assessment responsibilities and patient education to non-RNs. The commenter stated that both of these activities play a prominent role in ESRD patient care and the day-to-day operation of a dialysis facility, that courts are referencing with increasing frequency the standards of clinical practice developed by the various nursing specialty organizations, that nurses who practice substantially outside the range of these standards could be at risk if their clinical practice was called into question, and that decreasing the proposed rule content for nursing services could result in many RNs putting their nursing licenses on the line.

Response: The department acknowledges the comment. The department recognizes the concerns of other commenters relating to the increased costs in requiring an RN to be available to the treatment area at all times, and that there may not currently be a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules may diminish access to dialysis services and possibly force small businesses to close. Therefore, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The Board of Health charged the department to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes.

Comment: Regarding §117.43(e), one commenter stated that dialysis facilities are located in geographic locations where it will be difficult to fully staff with RNs, but these facilities are convenient to patients. The commenter fears these facilities may be forced to close because of these requirements. The commenter also believes that staffing times may change with these requirements, and patients may have fewer choices of times to dialyze, and have difficulty continuing to work.

Response: The department conducted a staffing survey to assess the current levels of staffing in dialysis facilities. Many commenters had expressed concerns that remote or rural facilities would not be able to staff all patient shifts with RNs. Review of a staffing survey conducted by the department showed that facilities with patient shifts in April 1996 that were not covered by an RN were primarily located in Austin, Houston, San Antonio, Beaumont, and Corpus Christi. The Texas Nurse's Association testified at the public hearing on May 9, 1996, that there are currently 80 programs that prepare RNs in Texas, with a program within 100 miles of every town in Texas. In addition, the ongoing reorganization of health care delivery systems has resulted in an increase in RNs available for work, particularly in larger cities. As part of an effort to determine the impact of these rules on the provision of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e), one commenter offered the following caveat to prove the point that it is safe for LVNs to dialyze patients: patient families are taught to dialyze their loved ones at home in six weeks; the person responsible for the dialysis is not even a nurse and the patient does fine. The commenter continued that dialysis is now refined and automated and it is not necessary to waste the efforts and resources of a fully trained nurse to supervise every minute of the dialysis treatment.

Response: The department does not agree that sharing responsibility for the treatment of one patient with that patient being primarily responsible for his or her own care is equivalent to being completely responsible for the care of a full shift of patients and the supervision of dialysis technicians. The improved machines, dialyzers and methods also mean that errors can quickly result in serious consequences. Patients deserve the efforts and resources of an RN to assure that safe effective care is delivered. However, to determine any impact of these rules on the provision of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e), one commenter stated it is better to have RNs training, educating, supervising, retraining, and counseling instead of providing direct care.

Response: The department agrees in part, and these rules require that the RN be assigned those responsibilities. The department also believes it is beneficial that RNs provide patient care. No change was made as suggested by the commenter, but changes were made to the requirements for nursing services based on other comments.

Comment: Regarding §117.43(e), one commenter stated that LVNs are in reality perfect for the day to day performance of the repetitive dialysis procedure as long as they are properly trained, and always know their doctors and RNs are available. A second commenter stated that an LVN with seniority in a clinic is a more valuable asset than an RN new to dialysis. A third commenter stated the limitation placed on LVNs by §117.43(e) will cause substantial increases in costs to facilities.

Response: The department agrees that the LVN is a valuable asset and expects facilities will continue to utilize these skilled nurses in direct patient care. Assigning LVNs responsibility for performing dialysis does not conflict with these rules. In addition, to determine any impact of these rules on the provision of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e), one commenter described how their facility is using their RN staff for patient education in the clinics with pre-ESRD education efforts to reduce the incidence of dialysis and better prepare patients for renal replacement therapy. The commenter stated it would be a shame to disrupt this wonderful program due to a shortage of RNs who have ample experience to perform chronic dialysis.

Response: The department commends these efforts to provide patient education earlier in the course of renal disease. These rules, however, address outpatient dialysis and the department believes that dialysis patients should also have the benefit of professional nursing. These rules do not require that every RN who provides care has previous dialysis experience. No change was made except as noted in response to other comments.

Comment: Regarding §117.43(e), one commenter stated that an individual's professional license can be used as a benchmark for general competency but it is not a complete analysis of a staff person's abilities. The commenter continued that medicine today is very complex in all areas; that nurses, like physicians, tend to concentrate their practice in one area usually chosen because of a high level of interest. The commenter added that LVNs who have worked in dialysis for several years are usually there because of an interest in nephrology and that LVNs can acquire an extensive knowledge base of this sub-specialty through their work environment. The commenter concluded that the assumption that a RN is more qualified that a LVN to assess a dialysis patient can not be based on professional licensure alone.

Response: The department agrees that qualifications are not necessarily based on professional licensure, but on the education that qualifies one to take the licensing exam. The department recognizes LVNs who are working in dialysis have valuable experiences; however, experience does not assure that one's knowledge base includes information needed to correctly assimilate those experiences. In order to determine any impact of these rules on the provision of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding proposed §117.43(e), one commenter stated some outpatient facilities do not employ RNs as leaders of the care delivery team but only as directors of nursing (DON). The commenter stated that under these circumstances, the DON is sometimes responsible for more than one facility, and may be the only RN staff member, adding that when clinical judgement is needed in respect to a patient's condition, either pre, intra, or post therapy, the RN is not available. The commenter concluded that this leaves other support personnel with the responsibility of making critical care decisions that they are neither educated nor trained to do.

Response: The department agrees and requires that a full-time supervising nurse be employed by each facility. In addition, responsibilities for the RN have been outlined at new §117.43(e)(3), and the responsibilities of the charge nurse are described at §117.44(c)(2). A three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The Board of Health charged the department to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes.

Comment: Regarding proposed §117.43(e), one commenter stated the licensing act for vocational nurses in Texas is a title protection act, that specific actions are not delineated because LVNs were never to be used in place of an RN but to perform certain tasks that would supplement RN practice. The commenter added that such tasks must be defined and delegated by the responsible party, which for nursing is the RN, and asked where does it leave the patient and how are the patient's outcomes affected if an RN is not present to evaluate the patient needs or make these critical decisions. One commenter asserted that dialysis is a complicated process that requires ongoing assessment of care, implementation of a plan of care, judgements about the care and outcomes, and monitoring and evaluating the care. The commenter added that an RN is educated to use a decision-making matrix called the nursing process to do just that. The commenter submitted that in the final rules the requirement for an RN to be in the center be retained as proposed. Another commenter expressed support for the RN requirement.

Response: The department acknowledges that the LVN licensing act is a title protection act, and agrees that an RN should be present to make evaluations of the patient needs. However, in order to determine any impact on the availability of dialysis services as a result of these rules, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e)(2), one commenter alleged the proposed rules will put qualified LVNs out of work and suggested the department be flexible by permitting LVNs currently employed to become RNs, by having different rules for facilities open at odd hours and for rural and small facilities, and by requiring the RN spend at least two of the four hours of each patient's treatment in the facility, but not necessarily in the treatment room. Another commenter suggested that current LVNs be "grandfathered" to allow the LVNs to obtain an RN license within a specific period of time. One commenter described staffing with LVNs and stated that their facility does not have a problem with quality. The commenter continued that several of the LVNs are in the process of attaining RN degrees, and that RNs are present in the facilities during the day, but not always on weekends, early mornings or late evenings. The commenter expressed concern that the LVNs would be displaced from their jobs by lesser experienced RNs. The commenter asked that the LVNs currently working in dialysis be "grandfathered" in for a period of three years while they obtain their RN degrees. An additional commenter stated that it is not practical to have an RN present every minute of every dialysis shift in every facility. The commenter requested that there be modifications to this rule to keep costs under control, but still maintain quality. The commenter suggested allowing RNs to cover at least three fourths of each treatment and that telemedicine be utilized to provide a facility access to RNs. One commenter declared to have been working with renal patients for 16 years and had not seen better quality care provided by

RNs than by LVNs. The commenter stated that in the rare emergency situations, an RN would have done what the LVN did and there would have been no different outcome.

Response: The department does not agree that the proposed rules would put qualified LVNs out of work but also recognizes that LVNs are presently acting in the charge capacity in many dialysis facilities. Two of these comments assume that one can predict the time patients will demonstrate a need for professional nursing assessment, planning, intervention and evaluation. Patients who dialyze at odd hours, in small facilities or in rural areas should be able to expect the same level of service any other patient receives; the department does not agree that different tiers of service should be created. Assessment of multiple patients on a minute-to-minute basis is not currently possible via telemedicine in the outpatient ESRD facilities in Texas. The department agrees in part with the commenters suggesting a "grandfathering" of current LVNs for a limited period of time; therefore, changes were made to the language in §117.43(e) and §117.44(c). The amended language in §117.44(c)(3) provides for a three-year phase-in period to allow the department to determine any impact the rules may have on patient access to dialysis services. This phase-in period will also allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. While it is not within the statutory authority of the department to outline a career ladder for any member of the renal care team, the department would certainly encourage facilities to support the professional growth of staff members, and this phase-in period may allow many LVNs currently working in dialysis sufficient time to complete the educational and testing requirements to obtain the RN credential. Additionally, the department has been charged by the Board of Health to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes.

Comment: Regarding §117.43(e), one commenter alleged the addition of more licensed staff would allow for much stronger quality of care, and recommended making a medication nurse a mandatory position for providing assessments, giving medications (with documentation of results), changing dressings, initiating and terminating dialysis treatments for patients with temporary accesses, providing patient education, and performing general documentation. The commenter stated that this position would provide emergency back-up to patient care providers in times of staff shortages. Two other commenters stated facilities over 20 stations should be required to have a medication nurse.

Response: The department acknowledges the support of the proposed rules but does not agree a medication nurse should be specified. The department recognizes the work load on licensed staff in administering an ever increasing number of medications during dialysis but believes that the language at renumbered §117.43(e)(5), (7), and (9) and at §117.44(c)(2)(A)-(D) provide some assurance that sufficient numbers of licensed nurses will be available to administer medications. The language was not changed as recommended by the commenters.

Comment: Regarding §117.43(e), one commenter suggested that experienced RNs should provide home dialysis (training).

Response: The department agrees and believes that language in §117.43(k)(1) sufficiently addresses this comment.

Comment: Three commenters supported the requirements at proposed §117.43(e)(1)-(3), particularly paragraph (e)(2) which requires the presence of an RN in the treatment area during all dialysis treatments. One of the commenters stated they have long been concerned about situations in Texas in which patients are being dialyzed and the only RN is off-site and available only by beeper. The commenter states that an RN cannot effectively conduct a patient or vascular access assessment over the phone. Regarding §117.43(e), an additional commenter stated that the staffing requirements are a step in the right direction and will promote quality of care for dialysis patients as a minimum standard. The commenter continued that the RN should be directly involved in the supervision of care and in the assessment of patients with ESRD on dialysis because of the great complexity of their conditions. In addition, the commenter stated that with the changes in health care, there are adequate numbers of RNs in the state to provide services in dialysis facilities, citing that there are over 80 programs available for the education of RNs with schools available within 100 miles of any location in the state, and concluded that the claim there are not an adequate number of RNs to provide the service may be unfounded.

Response: The department acknowledges the support but has amended the language to require an RN be available to the treatment area during all dialysis treatments with an exception for a three-year phase-in period added at §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The department believes that the additional specificity of RN responsibilities described in §117.43(e)(3) will help to assure the availability of professional nursing to all patients.

Comment: Regarding §117.43(e) and §117.44(c), one commenter strongly supported the need for an RN to be responsible for the nursing care at every dialysis facility, adding that the standards set for the supervising nurse are minimum and should not be decreased further. The commenter stated that "experience in dialysis" should not be interpreted too narrowly. The commenter added that nurses who have been working as career nephrology nurses in administration, regulation, teaching or research positions, but who have not been recent providers of direct patient care in a dialysis facility, could potentially be restricted from becoming supervising nurses. The commenter recommended that the definition of supervising nurse be broadened to allow substitution of certification in nephrology nursing for the 12 months experience obtained within the last 24 months.

Response: The department agrees and has broadened the definition of "supervising nurse" in §117.2 to allow substitution of current certification in nephrology nursing or in hemodialysis for the experience, to recognize both of the national certifications available to nurses working in hemodialysis. This substitution was also included in §117.44(c) describing the charge nurse's qualifications. To allow the department to determine the impact of these rules on the availability of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the

graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e), three commenters supported the role of the RN in the delivery of patient care and the need for the RN to be present whenever dialysis is being conducted. These commenters continued that technical competence is important, but is not enough. The commenters strongly supported the 1:10 licensed nurse to patient ratio with an RN preferred in that ratio and recommended a minimum 1:3 direct care staff to patient ratio or preferable acuity staffing ratio. The commenters also supported assessments before and after treatment to be performed by an RN, and requested that there be a definition of "charge nurse" to clarify how an LVN would be able to function in that role.

Response: The department has retained many of the supported standards of §117.43(e), with some amendments to provide greater flexibility while preserving parameters to promote quality nursing service. A description of RN responsibilities was added at §117.43(e)(3). The licensed nurse to patient ratio was changed to 1:12 to address concerns of other commenters. The direct care staff to patient ratio is now set to not exceed four patient per staff member, while the acuity-based staffing portion of the renumbered §117.43(e)(7) was deleted in response to other comments. Renumbered §117.43(e)(9) requires the assigned direct care staff member to evaluate each patient before and after treatment and report any question of change to the RN who would then conduct an assessment. A description of the responsibilities of the charge nurse was added at §117.44(c). To allow the department to determine the impact of the rules on the availability of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e), one commenter suggested the addition of "nursing services shall be provided to a patient and the patient's caregiver(s)."

Response: The department agrees that such addition would clarify that it is the facility's responsibility to provide nursing services to the patient to meet the patient's needs, as well as certain nursing services to the patient's family or significant other. The department has added new language in §117.43(e)(1) and reorganized the subsection accordingly.

Comment: Regarding §117.43(e) and §117.43(i), one commenter stated that there is not a shortage of nurses or social workers, but it is money which is going to be the determining factor whether new requirements are established or "business as usual" continues. The commenter added that it is the department's role to establish a policy for dialysis facilities and to consider federal money leaving Washington and coming to the State of Texas, to handle and to make sure this money is channeled to dialysis facilities in larger amounts and to make certain to use those monies to determine what type of patient care is going to be given by what type of professionals. The commenter concluded that the two top priorities of any elected or appointed official are the health and public safety of citizens, especially people on dialysis.

Response: The department understands the commenter's concern and acknowledges the comment.

Comment: Regarding §§117.43(e)(2), (3) and (5), 117.43(h)(5), and 117.43(i)(5), one commenter asked that the language regarding staffing ratios be stricken or at least relaxed significantly and instead of ratios, to concentrate on desired patient outcomes as a mechanism for facilities to perform up to the state's expectations. The commenter cited that one small facility dialyzing less than 25 patients, many of which are indigent, will close as of September 1, 1996, causing these patients to travel an additional 25 miles one way to receive their treatments. The commenter added in order for the commenter's three facilities to comply with the law or proposed rules the facility's costs will increase by approximately $180,000 spread out over approximately 160 patients in three different physical locations. According to the commenter, the $180,000 exceeds the combined taxable income of those same facilities in 1995. Another commenter contended that the changes required in staffing by these proposed rules would require a small facility with 12 machines to have one RN and at least one LVN or another RN. The commenter stated that besides being impossible to meet in rural areas, this is a death wish with regards to cost. The commenter also expressed concern about how time-off requirements would be met without having people to replace the licensed personnel on a routine basis.

Response: The department acknowledges that the imposition of a new set of rules for facilities is not without costs. The new rules will require new attention to patients in the form of increased and better trained staff and improved facilities. The possibility of facilities closing is of great concern to the department; therefore, the department solicited financial information from facility owners and managers in order to determine the accuracy of assessments such as the commenter's. The information received was not sufficient to reach a conclusion and facilities were justifiably reluctant to share competitive cost information, leaving the issue unresolved. In order to resolve this, the department obtained data on facility costs and revenues from a variety of sources: former facility administrators, clinicians (both in Texas and other states), federal officials, and others involved in the area of renal treatment and programming. This data demonstrated the implementation of these rules would impact, but not eliminate facility profit margins. Recognizing that facilities must remain profitable to remain open, the department has amended two of the more costly requirements of the proposed rules, providing a phase-in period for the requirement that an RN be present in the facility during all treatments and eliminating the staffing ratio for MSWs. The department also amended §117.15(g) to address the transition of existing facilities' compliance with the rules.

Comment: Regarding §§117.43(e), 117.43(h) and 117.43(i), one commenter stated that from a patient's perspective, dialysis consumes your whole life and disagreed with others who believe that the proposed regulations are not necessary, citing that technicians who may have worked in a department store before coming to work at the dialysis facility are allowed to insert needles into a patient's arm. The commenter expressed support for the dietitian requirements because of complex physical conditions affecting the dialysis patient such as diabetes, and the social worker requirement because the social worker

must focus on the patient and the family and what they're going through with dialysis. The commenter continued that when problems occur and when medications are needed, the staff turn to the RN because the LVN cannot provide this service. The commenter added that if a CEO from any dialysis center in the State of Texas or a member of their family were sitting in the dialysis chair they wouldn't want a technician, LVN or RN caring for them; they would want a doctor next to their chair for the entire treatment.

Response: The department acknowledges the commenter's support and notes that several changes were made to the sections referenced in response to other commenters.

Comment: Regarding proposed §117.43(e)(1), one commenter noted that a director of nursing (DON) ratio was not addressed and suggested that for facilities with more than 100 patients an assistant for the DON be required.

Response: The department does not believe the rules should address management ratios and has not changed the language.

Comment: Regarding proposed §117.43(e)(2), one commenter stated there is no justifiable argument against an RN being on the premises, or connected via telemedicine during the peak day hours.

Response: The department believes that the knowledge base and assessment skills of the RN are critical to positive patient outcomes. Assessment of multiple patients on a minute-to-minute basis is not currently possible via telemedicine in the outpatient ESRD facilities in Texas. Patients treated in off-peak hours deserve the same level of care as patients treated during peak day hours. To allow the department to determine the impact of the rules on the availability of dialysis services, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualifed LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding proposed §§117.43(e)(2), 117.43(e)(5), 117.43(h)(5), and 117.43(i)(5), one commenter opposed the staffing ratios in the rules, stating that having been involved in the legislation, the original intent of the law was "to prevent what had happened in Houston" referring to patients contracting hepatitis B positive status via dialysis. The commenter indicated the new law will "rule the way we practice medicine, or rule the way we practice nephrology in Texas," and expressed that in order to look at quality of care, one should consider the outcomes in each facility, develop a set of standards for outcomes and go from there. The commenter suggested the department look at mortalities, survival, morbidity, and hospitalization rates, and attempt to lower them if necessary, and if specific ratios are found to improve outcomes, this will be found out "soon enough."

Response: In response to concerns that patient access to dialysis services would be negatively impacted due to the financial impact of these rules, the ratio for MSWs was deleted and the staffing ratios for licensed and direct care staff were amended. As outcome measures are developed, validated, and accepted by the renal community, the department will revisit these rules, with the potential to omit the remaining staff ratio requirements for facilities that demonstrate excellent outcomes. After conducting initial surveys, the primary means of oversight by the department will be through the review of data such as the commenter suggests which will be collected as an annual report. Due to concerns regarding the changes made to the proposed staffing levels, the Board of Health charged the department to monitor facilities for evidence of any impact staffing levels may have on patient care and outcomes during the three-year period which is now provided for the gradual implementation of the requirement that the charge nurse be an RN.

Comment: Regarding §117.43(e)(2), one commenter objected to the requirement that an RN be in the treatment area when patients are being treated, citing that many LVNs have been providing dialysis care for many years and are as competent on the floor as many of the RNs. The commenter stated that the RN needs to be with them and be made available for assessment for emergency care, but not necessarily sitting by doing sometimes nothing at the nurse's station. One commenter requested that an LVN be included in this proposed rule. Four commenters stated it was unreasonable to have an RN in the treatment area at all times; in a small facility this would require two RNs each day to be present to allow for lunch and breaks. Another commenter alleged that it is not feasible to have an RN in the dialysis facility at all times for rural areas and asked that the rule be modified to say the RN shall be available to the treatment area at all times. One commenter requested the requirement be changed to allow an RN or an LVN in the treatment area at all times, with the LVN providing immediate trouble shooting and the RN standing by where indicated. Another commenter stated that his facility currently has an affiliate facility with 20 patients that is 60 miles away, that this facility cannot afford to have a second RN in the building in order to have the primary RN to take a break or eat, and recommended the department include language to allow facilities to have an RN in the building rather than in the treatment area. One commenter stated it would detract from the value and quality of the program if RNs had to be taken away from teaching positions in order to meet the demands of this "unreasonable" rule. Another commenter suggested changing the wording in proposed §117.43(e)(2) to allow the RN to be "on the premises at all times" rather than in the treatment area, stating that it is sufficient to have expertise on the premises and not at the bedside at all moments during treatment.

Response: In response to these and other comments, the language was amended to require a charge nurse to be "on site and available to the treatment area to provide patient care during all dialysis treatments." Having RNs present in the treatment area will enhance rather than diminish their opportunities to teach. However, to allow the department to determine the impact of the rules on the availability of dialysis services, a definition of "charge nurse" was added in §117.2 and an exception was added in §117.44(c)(3) which provides a three-year phase-in period during which a qualifed LVN may function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: One commenter alleged the rules at proposed §117.43(e)(1) and (2) do not follow the designs of the legislators who crafted the licensing law.

Response: The department does not agree. The statutory language, developed by the legislature, limited the role of LVN's by requiring them to qualify as technicians and charged the department with responsibility of crafting rules regarding the provision of treatment and services and qualifications of staff. The department is concerned that there may not currently be a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules may diminish access to dialysis services and possibly force small businesses to close. Therefore, a three-year phase-in period has been provided in §117.44(c)(3) to allow an LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding proposed §117.43(e)(2), two commenters quoted research being published by Sherry Bame of Texas A&M University which was conducted in Texas dialysis facilities from 1991-1994. The commenters stated that this study demonstrated a significant decrease in the likelihood of patients dying by increasing the ratio of RNs providing care. According to the commenters, the study showed that for each RN that was added, there was a greater than 60% reduction in the patient's likelihood of dying. Another commenter stated that Ray Hakim, MD, a speaker at the Network annual meeting in Dallas on April 12, 1996, presented data to support the influence of RNs on positive patient outcomes.

Response: The department acknowledges the information. The department recognizes that there are increased costs in requiring an RN to be available to the treatment area at all times, and that there may not currently be a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules may diminish access to dialysis services and possibly force small businesses to close. Therefore, a three-year phase-in period has been provided in §117.44(c)(3) to allow an LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The Board of Health charged the department to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes.

Comment: Regarding proposed §117.43(e)(2), one commenter acknowledged that there has been some suggestion that there are not enough RNs to support the rule requirement, and stated that there is no data to support this suggestion, continuing that recent graduates of nursing schools within the state are finding it difficult to find jobs. The commenter added that care redesign in hospitals across the state has left professional nurses without jobs, and cited that some nurses in one hospital's dialysis facility have had to submit to recent benefit changes because "they had no where to go."

Response: The department acknowledges the comment but has provided a three year phase-in period for the requirement that the charge nurse be an RN to assure that access to dialysis services is not impeded due to the implementation of these rules.

Comment: One commenter asked if proposed §117.43(e)(2) was meant to include the charge nurse.

Response: Licensed nurses functioning in the charge position are not excluded by the rule. The rule was renumbered §117.43(e)(4).

Comment: Regarding proposed §117.43(e)(2), three commenters asserted that a nurse should be available in the facility, or available to the treatment area to provide patient care at any time during all dialysis treatments. One of these commenters expressed concern that in smaller facilities, with only one RN on duty, that nurse would not be able to go to the bathroom or take a break, and having two RNs on duty in that situation is not economically feasible. Another commenter asked that the requirement be amended to read "an RN shall be available in the facility to provide patient care in the event of an emergency." One other commenter expressed concern that requiring the RN to be present in the treatment area at all times would preclude the RN from having a break, and asked that the language be amended to have the RN be present in the facility at all times and accessible to the treatment area. Another commenter stated not every facility has access to or can contract with RNs to meet the proposed regulations.

Response: The department recognizes that some facilities may have to recruit additional RNs. Given the current reorganization of health care delivery systems, there is a greater availability of RNs than in the past. The department also believes that the provisions of these rules will improve the working conditions in dialysis facilities by requiring standardized training for dialysis technicians, by assuring that professional nursing care and supervision is continuously available, and by providing better access to the support services of nutritional and social work. These improved working conditions may result in less turnover of staff, resulting in cost savings for facilities. Further, availability of a nurse should not depend on a patient emergency; the nurse should be available to provide patient care whenever a question of change in patient status occurs. The department had no intention to preclude a single RN from taking a break. To address the concerns of this and other commenters, the language of this rule was amended to require a "charge nurse" be present and was renumbered §117.43(e)(4). A definition of a charge nurse was added to include the use of a qualified LVN during a three year phase-in period to allow the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding proposed §117.43(e)(2), one commenter supported the standard for an RN to be on duty when dialysis is being performed and 19 commenters supported the standard for an RN to be in the dialysis treatment area at all times. Another commenter strongly supported having an RN in the treatment area as it is consistent with quality of care. This Texas professional nurse's organization stated that adequate numbers of RNs are available to meet this requirement, as Texas has nursing programs in all areas of the state including rural areas. The commenter suggested addressing the concerns of those who believe that all facilities would have to employ two RNs to allow the RN to take a break by prescribing that 80% of the time the RN would need to be in the treatment area. Another commenter supported the rule requiring an RN be available in the treatment area to provide patient care during all dialysis treatments, based on personal clinical experiences in the dialysis setting. The commenter stated although he has worked with many tal-

ented and skilled dialysis LVNs, with the growing complexity of medical problems of the average dialysis patient it is imperative to have a medical professional who has been educated and prepared for the multiple complications and incidents often arising during the dialysis procedure. The commenter presented the American Nurse's Association's (ANA) Model Practice Acts for RNs and LVNs to support his comment. The ANA defined the practice of the RN as "a process in which substantial specialized knowledge derived from the biological, physical and behavioral sciences is applied to the care, treatment, counsel, and health teaching of persons who are experiencing changes in the normal health process; or require assistance in the maintenance of health or the management of illness, injury...," and defined the practice of the LVN as "performing under the supervision of a RN of those services required in observing and caring for the ill, injured or infirm, in promoting preventative measures in community health, in acting to safeguard life and health, in administering treatment and medication prescribed by a physician...or in performing other acts not requiring skill, judgement, and knowledge of the registered nurse." One other commenter stated that it is critical to have an RN on site during dialysis.

Response: The department acknowledges the support and appreciates the information regarding the availability of nursing programs and the ANA Model Practice Acts. However due to concerns that the implementation of these rules could diminish access to dialysis services and possibly force small businesses to close, a three-year phase-in period has been provided in §117.44(c)(3), allowing a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The Board of Health charged the department to monitor facilities during this three-year period for evidence of any impact staffing levels may have on patient care and outcomes.

Comment: Regarding proposed §117.43(e)(2), one commenter related that 75% of the patients in their facility would be eligible for home care if they had a willing partner, and home patients do not see an RN every treatment.

Response: The department does not agree that sharing responsibility for the treatment of one patient with that patient being in charge of his or her own care is equivalent to having the duty of caring for a full shift of patients and the supervision of dialysis technicians. The language was amended to require a "charge nurse" be present, and the definition of a charge nurse includes the use of a qualified LVN during a three year phase-in period during the graduated implementation of the requirement that the charge nurse be an RN and was renumbered §117.43(e)(4).

Comment: Regarding proposed §117.43(e)(2), 10 commenters suggested an RN be available in the treatment area to provide patient care during all dialysis treatments or when unavailable and with written notification of department, a licensed nurse shall be available in the treatment area to provide patient care during all dialysis treatments.

Response: The commenters did not explain the purpose of notifying the department that the services of an RN were not provided. The language was amended to require a "charge nurse" be present, and the definition of a charge nurse includes the use of a qualified LVN during a three year phase-in period during the graduated implementation of the requirement that the charge nurse be an RN and was renumbered §117.43(e)(4).

Comment: Regarding proposed §117.43(e)(2), one commenter stated that if the requirement for an RN in the treatment area is deleted, the department should indicate the supervisory responsibility of the RN and that those responsibilities be consistent with the Nurse Practice Act and the Board of Nurse Examiners' rules related to the practice of nursing. The commenter expressed concern about a dialysis technician serving as a preceptor if an RN is not in the treatment area.

Response: The department has included language at §117.44(c)(3)(C) to require the full-time supervising nurse establish written protocols addressing the supervision of technicians when a qualified LVN is functioning as a charge nurse. The implementation of the protocol shall be considered to constitute direct supervision of the technicians by the RN.

Comment: Regarding proposed §117.43(e)(1) and (2), one commenter stated that nursing services do not include a list of general responsibilities for the supervising RN or for the RN in the treatment area, while a list exists for all other members of the care team. The commenter stated that the responsibility for "participating in a team review of the patient's progress" is not included in the role of medical director or as a responsibility for the RN.

Response: The department agrees that this was an oversight and has added a list of responsibilities for RNs in §117.43(e)(3) which includes "participating in a team review of the patient's progress," and for the charge nurse in §117.44(c)(2). The requirement for physician participation in care planning applies to the patient's primary physician rather than the medical director. The department reorganized the section, renumbering proposed §117.43(e)(1) and (2) as §117.43(e)(2) and (4).

Comment: Regarding proposed §117.43(e)(2), one commenter stated there should be at least one licensed nurse available at all times in the treatment area and that a nurse filling out paperwork is not providing patient care nor are the members of the staff with no medical training, such as technicians, who have been trained in the use of the machinery. The commenter concluded that an RN or LVN should be in direct contact with the patients on a daily basis and believed a family member might have lived longer if he had been looked after by a nurse.

Response: The department agrees with the commenter and has reworded the requirement at renumbered §117.43(e)(5) to require a "charge nurse" (who could be an RN or an LVN) to be on site and available to the treatment area at all times and added a list of charge nurse responsibilities at §117.44(c)(2) to assure that most of this nurse's time is spent in the treatment area.

Comment: Regarding proposed §117.43(e)(2)-(3), one commenter agreed with the RN being required to be in the treatment area, but wanted a 1:12 licensed nurse to patient ratio rather than 1:10.

Response: The department has amended the language renumbered at §117.43(e)(4) to require a "charge nurse," who could be an RN or an LVN, be "on site and available to the treatment area," and added charge nurse responsibilities at §117.44(c)(2).

In response to this and other comments, the department has changed the licensed nurse to patient ratio to 1:12.

Comment: Regarding proposed §117.43(e)(3), one commenter explained that in a fiscal environment involving managed care and severely insufficient Medicare reimbursement it would not be possible to just hire the number of RNs needed. A facility would have to terminate the employment of several excellent LVNs who have provided years of high quality service to patients who are very attached to the patients. The commenter continued that while he admired the efforts of nursing organizations to ensure jobs for RNs, there are just too few RNs experienced in dialysis to go around, and the number of RNs that these rules would require is superfluous.

Response: The department disagrees that having one RN per patient shift is superfluous. The requirement at renumbered §117.43(e)(5) can be met using a mix of RNs and LVNs, which will encourage facilities to retain LVNs, preserving the resource of their experience. Due to concerns that the implementation of these rules could diminish patient access to dialysis services and possibly force small businesses to close, a three-year phase-in period has been provided in §117.44(c)(3), allowing a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Regarding proposed §117.43(e)(3), one commenter stated that it is necessary to have at least one RN per six patients in the facility during all treatment hours; seven commenters recommended this standard be adopted with the additional requirement that 50% of these licensed nurses be RNs; one commenter stated that the language should be omitted, as the other sections adequately cover the patient care issues and a specific designation of nurse per patient is not necessary, giving the example that a facility may have 11 or 12 stations, and asking if that facility would have to staff with two licensed individuals. Three other commenters asked that the rule be amended to require one licensed nurse for every 12 patients; one of these commenters explained the 1:12 ratio is better because of the way many dialysis facilities are set up. Another commenter concluded that the 1:12 ratio better coincides with the 1:4 direct care staff to patient ratio in proposed §117.43(e)(5). Four commenters stated they did not believe that proposed §117.43(e)(3) requiring a licensed person for every 10 patients is necessary. Two commenters stated they were for the 1:10 licensed nurse to patient ratio described in proposed §117.43(e)(3). Another commenter stated that the requirement for at least one licensed nurse to be available for every 10 patients or portion thereof should be a minimum requirement which will greatly improve the quality of patient care in dialysis facilities. One commenter contended that one RN on site for every 10 patients is excessive, that it goes beyond HCFA requirements, would seriously impede a facility's ability to staff, put dialysis technicians out of work, and cause financial hardships on the facility. The commenter asked that the department consider all of this in conjunction with the reduced Medicare reimbursement to facilities. One commenter asserted that the LVN is a valuable member of the care team, and it would be very helpful in larger facilities to have one LVN per every 10 patients, with two patient care technicians and an RN in charge over all. Other commenters supported the 1:10 ratio.

Response: The department does not agree that every facility needs one RN per every six patients or that specifying that 50% of the licensed personnel on duty should be RNs. However, in response to these and other comments, the ratio of licensed staff to patients was changed to 1:12. Each facility will need to review the needs of the patients they serve and set staffing parameters to meet these needs in a manner consistent with the rules. Dialysis facilities require licensed personnel to meet the needs of today's outpatient dialysis population where it is routine to administer multiple intravenous medications; with the exception of normal saline, heparin or lidocaine, administration of medications is a prohibited act for dialysis technicians under §117.65(b)(2). The department agrees that the LVN is a valuable member of the care team and assumes that many facilities will be utilizing LVNs in meeting the ratio. The department also amended the rule to clarify that the RN described in renumbered paragraph (e)(4) may be included in the licensed nurse to patient ratio. The rule proposed at §117.43(e)(3) was renumbered as §117.43(e)(5).

Comment: One commenter expressed confusion about the use of the term "licensed nurse" in the requirement at proposed §117.43(e)(3), and stated they thought that "licensed nurse" should read "registered nurse" to avoid confusion.

Response: The department does not agree. Both RNs and LVNs are licensed; either would meet this requirement for licensed nurse. The language was renumbered §117.43(e)(5).

Comment: One commenter suggested that the language in proposed §117.43(e)(3) be changed to "adequate licensed staff shall be available on-site to provide patient care." The commenter stated the current patient census at their facility at the end of 1995 was 1,350 in-center patients, and they had 186 direct patient care staff to include 41 RNs, 20 LVNs, and 125 patient care technicians. According to the commenter these numbers provide 33% licensed staff and a ratio of 1:11 licensed staff to patients. The commenter stated the 1995 salary expense for direct patient care RNs and LVNs was $2,600,261 (including benefits), representing an average annual salary of $42,627 for each nurse. The commenter continued that in order to provide one licensed nurse for each 10 patients the commenter would have to increase the nursing staff by seven to a total of 68 nurses and with 1995 salary rates, this would increase their direct patient care personnel cost by $298,389 per year. The commenter concluded that they have used their current staffing guidelines for at least 10 years and have managed to provide quality care for patients.

Response: The department appreciates the detail of this comment and recognizes that the requirement for specific ratios will result in increased costs to the providers of dialysis services. The accepted measurable indicators of quality in dialysis are fairly limited at this time. As these are defined by the renal community, the department will revisit this issue with the possibility of deleting the requirements for direct care staffing ratios in those facilities which demonstrate excellent outcomes. In response to this and other comments, the department has amended this language to require a 1:12 licensed nurse to patient ratio.

Comment: Regarding proposed §117.43(e)(5) and (7), one commenter strongly supported the 1:10 licensed nurse to patient ratio, the minimum 1:4 direct care staff to patient ratio, and RN assessment of all patients before and after treatment.

Response: The department agrees in part and the direct care staff to patient ratio of 1:4 was retained at renumbered §117.43(e)(7). In response to other commenters concerns that patient access to dialysis treatment would be impeded due to the financial impact of some of these requirements, the licensed nurse to patient ratio was increased to 1:12 and the requirement for an RN to be present in the facility during all treatment times will be phased-in over a 3 year period.

Comment: Regarding §§117.43(e)(3), 117.43(e)(5), 117.43(h)(5) and 117.43(i)(5), five commenters recommended staffing be determined by the efficiency of the staff member instead of being regulated by law, there is not sufficient evidence that staffing ratios impact outcomes, ratios may take away independence with creative work designation, ratios cannot eliminate or protect patients from hepatitis, outcomes should be used instead of ratios, and each facility should be able to simply employ or contract with a social worker(s) to meet the psychosocial needs of the patients.

Response: In response to this and other comments, the department has amended the language regarding the ratios for licensed staff at §117.43(i)(5) and deleted the ratio for MSWs at renumbered §117.43(e)(7). The accepted measurable indicators of quality in dialysis are fairly limited at this time. As these are defined by the renal community, the department will revisit this issue with the possibility of deleting the requirements for direct care staffing ratios in those facilities which demonstrate excellent outcomes.

Comment: Regarding proposed §§117.43(e)(3) and 117.43(e)(5), one commenter stated nursing and staff ratios do not improve quality or ensure quality of care and some rural facilities will have a difficult, if not impossible time meeting these licensed nurse provisions. One commenter expressed that these staffing ratios for nursing services, social services at §117.43(i)(5), nutritional services at §117.43(h)(5), and the establishment of an acuity based assessment system, should not be used and proposed that subjective and objective data be closely monitored through the established Network Criteria and Standards and through these monitored results, corrected interventions on a facility to facility basis be made.

Response: While the department agrees that mandating certain ratios will not guarantee improvements in the quality of care ESRD patients receives, the department believes ensuring adequate staffing numbers will allow patients to be monitored more closely, have problems recognized earlier and receive earlier intervention to prevent adverse outcomes. The department does not agree with the commenter's statement that rural facilities will have a difficult time meeting the licensed nurse provisions of this section. A staffing survey conducted by the department determined that during the month of April 1996, facilities which had patient shifts not covered by RNs were primarily located in Houston, Austin, San Antonio, Corpus Christi, and Beaumont. More rural units reported being able to cover all shifts with RNs. The department retained the 1:4 direct care staff to patient ratio at the renumbered §117.43(e)(7) and has amended the language to allow a licensed nurse to patient ratio of 1:12 in response to this and other commenters at the renumbered §117.43(e)(5).

Comment: One commenter suggested the sentence at proposed §117.43(e)(4) be ended after the phrase "pediatric dialysis patients" as the language currently following that phrase is inconsistent with the definition of "pediatric patient" in §117.2. The commenter stated there were other sections, such as §117.65(b)(7) where the parameters for pediatric patients are in conflict with the definition.

Response: The department acknowledges the differences between the definition of "pediatric patient" and the provision of nursing and medical services to specific age groups in the rules. Because of concerns regarding the availability of RNs with pediatric experience and with the advise of the MRB, the parameters described in renumbered §117.43(e)(6) were broadened to require an RN with experience or training in pediatric dialysis to be available to provide care for pediatric dialysis patients younger than 14 years of age or smaller than 35 kilograms in weight. The department does not believe that the differences are conflicts, but serve to assure special attention is given to pediatric patients under 14 years or smaller than 35 kilograms in weight.

Comment: One commenter recommended the addition of "if pediatric dialysis is provided" in proposed §117.43(e)(4).

Response: The department agrees and made the addition, renumbering the rule at §117.43(e)(6).

Comment: Regarding proposed §117.43(e)(4), four commenters suggested that the adolescent patient should not be excluded from the requirement that an RN with experience or training in pediatric dialysis be on site. One commenter wanted more guidelines for the care of adolescent patients for the unique medical, social, emotional, psychological, and nutritional issues related to this age group.

Response: The department has extended the age requiring a nurse with experience or training in pediatric dialysis to 14 years of age in renumbered §117.43(e)(6), which will provide some coverage for adolescent patients. Further, the department believes that the addition of language requiring facilities to adopt, implement and enforce policies and procedures "appropriate to the patient population served" in §117.43(a) is sufficient to address the commenter's concerns.

Comment: Regarding proposed §117.43(e)(4), one commenter suggested that an RN with pediatric experience might not be required for patients under 29 kilograms, and this issue should be decided on an individual basis.

Response: The department disagrees after receiving information from pediatric nephrologists and nurses relating to parameters for pediatric care. The department agrees with the commenter that each patient should be evaluated on an individual basis with the requirements in these rules serving as minimum standards. The language was amended in renumbered §117.43(e)(6).

Comment: One commenter stated that experience in serving the dual role of director of nursing and area manager of dialysis facilities leads to suggest that the department should reconsider

the language about the acuity based assessment described in proposed §117.43(e)(5). The commenter stated that she agreed with others to staff according to patient outcomes, but believed that it was necessary to continue to address staffing ratios and acuity. The commenter requested the department define the meaning of the term "acuity based," adding that in a dialysis facility, patients have different acuities from day to day and questioned how a facility can be staffed based on such a fluid acuity level. The commenter was concerned that department survey staff would not evaluate acuity levels consistently and whether the review would be based on scheduled acuity or actual acuity.

Response: The department agrees that there are differences in acuity-based staffing systems, and that no one system has been accepted and utilized by the dialysis community. Therefore, the language related to acuity-based assessment for staffing levels was deleted, and the minimum staffing ratio of 1:4 staff to patient was maintained in renumbered §117.43(e)(7).

Comment: Regarding proposed §117.43(e)(5), one commenter stated that a minimum of 1:3 or 1:3.5 staffing should be provided, and expressed concern that with all this added documentation they have to be allowed time to continue to provide adequate patient care. The commenter stated that employees who work three patient shifts per 12-hour day find it is too demanding for a patient care technician to have a 1:4 ratio all day long, and that it sets up an environment to promote error. The commenter asked the department to consider patient safety and staff hours.

Response: The department acknowledges the comment, but has responded to other commenter's concerns that patient access to dialysis treatment would be impeded due to the financial impact of some of these requirements and maintained the proposed 1:4 staff to patient ratio as the maximum patient assignment for any direct care staff member at renumbered §117.43(e)(7).

Comment: Seven commenters asked if the text in proposed §117.43(e)(5) meant that direct patient care staff can care for more than four patients.

Response: The department agrees that the language of this standard was not clear, and has rewritten the language to use "shall not exceed" rather than "at a minimum." The rule was renumbered §117.43(e)(7).

Comment: Six commenters supported the nurse to patient ratios specified in proposed §117.43(e)(5) for pediatric patients weighing less than 10-20 kilograms.

Response: The department acknowledges the support for this standard.

Comment: Regarding proposed §117.43(e)(5), one commenter asked who would develop the acuity-based system and what would be the guidelines. The commenter described their facility as a small facility with 10 stations and 30 patients and said that in order to meet the total facility productivity set by the employers, direct patient care staffing must be 4:1. The commenter continued that the one nurse for the shift is expected to be the charge nurse, medication nurse, administer one to two treatments, and supervise two patient care technicians with four patients each. The commenter stated that if the doctor makes rounds, this nurse is supposed to accompany the doctor, with hopes that "the day is uneventful." The commenter believes the issue of staffing for the good of the patient is being ignored.

Response: The department has deleted the requirement for acuity-based staffing at renumbered §117.43(e)(7) in response to this and other questions of how that system would be defined. The requirement for direct care staffing was reworded to clarify that this ratio was not to exceed 1:4 staff to patients.

Comment: Regarding proposed §117.43(e)(5), one commenter expressed opposition to ratios, and suggested the use of acuity measures. Another commenter expressed difficulty in establishing and maintaining a consistent acuity system. One commenter stated that acuity based staffing is excellent, but needs to be defined.

Response: The department acknowledges the support of the proposed requirement for staffing to reflect acuity measures renumbered as §117.43(e)(7), but disagrees that ratios are not necessary. Minimal work on the development and use of acuity measures in outpatient dialysis has been reported in the literature, and the majority of commenters expressed concern and insecurity with being required to implement untested systems that might not be effective. Facilities are free to develop acuity-based staffing systems, and, when the specifics have been worked out and the programs have demonstrated ability to provide flexibility in staffing, the department will reevaluate the requirements for ratios.

Comment: Regarding §117.43(e)(5), 166 commenters recommended the language be amended to provide a 3:1 patient to direct care staff ratio.

Response: The department acknowledges the commenters, over a 100 of whom were patients, but has reworded the requirement to make it clear that the staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift. The acuity assessment system language was deleted because of the inconsistency in developing such a system. The rule was renumbered as §117.43(e)(7).

Comment: Regarding proposed §117.43(e)(5), five commenters asked if recommending the RN care for four patients and still be accountable for the assessments before and after treatment proposed in §117.43(e)(7) was a realistic, safe expectation.

Response: The department agrees with the commenter and has amended the language to address this concern in renumbered §117.43(e)(7) and the renumbered §117.43(e)(9). Additionally, in response to concerns that the cost implications of some of these rules would impede patient access to dialysis services, the requirement for an RN to be present in the facility during all treatment times will be phased-in over a 3 year period.

Comment: Regarding proposed §117.43(e)(5), one commenter stated they were against RN ratios.

Response: The rules do not include RN ratios. Until patient outcome measures are standardized and accepted, the ratios defined for licensed nurses and for direct care staff serve as one method to provide a minimum level of care.

Comment: Regarding proposed §117.43(e)(5), two commenters suggested the licensed nurse to patient ratio be removed in favor of requiring adequate licensed staff to meet patient needs. One of the commenters added that the department surveyor can make that judgement and if there is disagreement the Network MRB can be consulted.

Response: The department does not agree. There is not uniform agreement among the members of the renal community as to what "adequate staffing" means, and a surveyor's identification of significant outcomes related to "inadequate" staffing is difficult to impossible within the time constraints of a two-day survey process. The MRB will be serving in an advisory capacity when quality of care issues are identified, but there is no intent, need or statutory requirement to ask them to review routine surveys. In response to other comments, the licensed nurse to patient ratio was amended to 1:12.

Comment: Regarding proposed §117.43(e)(5), one commenter stated the RN ratios did not make sense; that experience had shown "that we could train just about anybody to do chronic dialysis."

Response: The department does not agree and has maintained the requirements for experienced and trained nursing staff at renumbered §117.43(e)(5) and (7).

Comment: Regarding proposed §117.43(e)(5), one commenter stated that the new regulations would make it necessary to change from their current 1:3 staffing to at least a 1: 4 or 1:5 ratio. The commenter stated their facility has five LVNs, two of whom are used as charge nurses at various times and that if facilities must have an RN on the floor at all times and there is no distinction between an LVN and a dialysis technician, these LVNs will probably be laid off as the facility will not be able to pay the higher salaries if their licenses are not utilized. The commenter added that a majority of these LVNs have a minimum of five years experience in dialysis facilities and RNs in dialysis are difficult to find and keep even in large cities.

Response: The department does not agree that there is no distinction in these rules between an LVN and a patient care technician. Although the statutory language grouped LVNs with patient care technicians under the term "dialysis technician," the rules have included LVNs in meeting the ratio at renumbered §117.43(e)(5), and have not precluded LVNs from functioning in accordance with their license (§117.43(f)). The department expects that LVNs will continue to provide valuable service to renal patients. In addition, in order to assure that the availability of dialysis services is not negatively impacted by these rules, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: One commenter stated the acuity based assessment system required by proposed §117.43(e)(5) is not practical for a dialysis facility; a patient's acuity rating may change from one day to the next, even one minute to the next, and staffing is done weeks in advance. The commenter requested the department delete everything at this requirement except "sufficient direct care staff shall be on site to meet the needs of the patients."

Response: The department agrees with the commenter regarding the acuity based assessment system and has deleted that language. The department does not agree with deleting the remainder of the rule but has amended the language in response to other comments; the rule was renumbered as §117.43(e)(7).

Comment: One commenter explained that their facility provides three levels of dialysis services (self care, intermediate care, and full care) and each has a different staffing ratio; for example the staffing ratio for self-care is 1:6, as these patients set up their own machines, monitor their own dialysis and clean up the area when they are finished. The commenter stated that this program was started to be as close to home dialysis as possible, citing that studies have shown the more the patient is involved in their own care the longer their survival. The commenter concluded that requiring a 1:4 ratio as described in proposed §117.43(e)(5) would make this level of service more expensive and less viable.

Response: The department agrees that patients involved in their own care survive longer, and believes the requirements at §117.43(a) and (b) will promote facilities encouraging patients to be involved. The department is reluctant to offer options for other ratios for self care patients, as the surveyors have noted "self care" patients in some facilities are not more independent in their care than other patients, and is concerned that the designation may have had more to do with reimbursement benefits than level of care.

Comment: Regarding proposed §117.43(e)(5), one commenter contended that a ratio of one direct care staff member to every four patients is acceptable only when patients are less ill and able to assist with their care and that a one to four ratio creates a strain on licensed staff when there is increased acuity of care, educational and emotional support, time needed for assessments, and documentation.

Response: The department appreciates the comment. Due to other commenter's concerns that the financial impact of some of these rules would impede patient access to dialysis services, the department has amended the language to clarify that the staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift and renumbered the rule at §117.43(e)(7).

Comment: One commenter supported the requirements at proposed §117.43(e)(5) and assessments by RNs in proposed §117.43(e)(7) and asked for clarification to define whether facilities will be expected to demonstrate an acuity system for the staffing based on scheduled treatments or actual treatments delivered.

Response: The department has deleted the requirement for acuity based staffing at renumbered §117.43(e)(7) and made changes to the requirement for RN assessment at renumbered §117.43(e)(9).

Comment: Ten commenters asked to delete the word "licensed" and put in the word "registered" in proposed §117.43(e)(5) relating to the nursing requirement for pediatric patients.

Response: The department disagrees and believes the rule renumbered at §117.43(e)(7) sufficiently addresses the need to provide RN coverage if pediatric patients are included in the facility's census.

Comment: Regarding proposed §117.43(e)(5), two commenters asked the department to make a 3:1 patient to staff ratio mandatory, stating the acuity based system will not work in an outpatient dialysis facility because patients' conditions change on a daily to hourly basis and it would be impossible to staff for this. One commenter described working with a 3:1 ratio, and seen the acuity concern balance itself when that ratio is used. The commenter described the dialysis population as older now, and as presenting with a variety of complex health issues such as end-stage cardiac disease, cancers, diabetes with blindness and amputations, peripheral vascular disease and strokes. The commenter added that when a staff member must set up for and put four patients on dialysis, dialyze them four to four and one-half hours, take them off, strip and clean the machines, stabilize the patients, set up four machines, discharge the patients and start over again, "you don't get quality, you get by" and that there is no time left to encompass the patient as a whole to meet their needs. The commenter continued that some think a 3:1 ratio does not make good business sense, but there will be fewer on-the-job injuries, greater job satisfaction, less care givers looking for a quick way out, and an increase in staff retention (less time and money will be wasted on staff members who resign two months out of training). Two commenters recommended a 3.5:1 patient to direct care staff ratio. Seven commenters stated it would be more appropriate to require a 3:1 ratio and eliminate the acuity assessment system language. This would provide sufficient numbers to staff adequately, as is defined for pediatrics. The commenters stated that patients are getting older and sicker, needing more care while on dialysis, thus a ratio of 3:1 will be sufficient to provide the kind of care these patients have long deserved. The commenters expressed they believed the department will be heading in the right direction when staffing is based fairly to provide quality care. One commenter stated that an acuity based staffing system is a manager's nightmare, as patient acuity changes from day to day, shift to shift, even hour to hour. Another commenter expressed similar concerns. The first commenter stated that large corporations are not going to allow sufficient staff to be hired to properly manage an acuity based staffing system, and it is difficult to find a sufficient number of people who are willing to work on a schedule where hours and work times are difficult to predict. The commenter suggested instead that the department require a 3:1 ratio. The commenter stated that their facility maintains 4:1 staffing just to allow for a separate medication nurse, which is a necessity in their facility which dialyzes up to 33 patients at one time.

Response: The department agrees in part and has deleted the acuity assessment system in renumbered §117.43(e)(7). Due to other commenter's concerns that the financial impact of some of these rules would impede patient access to dialysis services, the department has amended the language to clarify that the staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift and renumbered the rule at §117.43(e)(7).

Comment: Concerning proposed §117.43(e)(5), one commenter stated the 4:1 ratio was acceptable, but should exclude the director of nursing and the charge nurse.

Response: The department does not agree that any nurses should be excluded from the ratio, unless that nurse is not available to provide patient care. The department has amended the language of the requirement in renumbered §117.43(e)(7) in response to other commenters.

Comment: Regarding proposed §117.43(e)(5), two commenters asserted that ratios do not assure quality and that staffing of nurses and technicians should be based on patient care needs. Four commenters stated they were against the 4:1 ratio.

Response: While the department agrees there is more to quality than ratios, and that staffing should be based on patient care needs, the department disagrees with the implication to delete them. The requirement for minimum ratios is meant to assure a level of staffing to meet the needs of most patients. As consistent outcome measures are developed, validated, and accepted by the renal community, the department will revisit these rules, with the potential to offer options to facilities that demonstrate excellent outcomes.

Comment: Regarding proposed §117.43(e)(5), one commenter supported the inclusion of an acuity-based assessment system in the proposed rules, stating this helps identify trends and plan for matching resources with work load.

Response: The department has responded to other commenters by deleting the requirement at renumbered §117.43(e)(7) for acuity based staffing. If acuity based assessment systems become more widely and consistently applied in outpatient dialysis, the department will revisit this issue.

Comment: One commenter asked that the requirement at proposed §117.43(e)(5) specifying "from 10 to 20 kilograms" be amended to read "developmental chronological age."

Response: The department disagrees because the suggested language is not sufficiently clear to provide direction for facilities which provide care to pediatric patients

Comment: One commenter stated that acuity measures, as required by proposed §117.43(e)(5) may be of some benefit in an acute setting but in a chronic setting they are of no significant benefit. The commenter continued that she had worked with acuity measures in acute and chronic settings; because acuity measures work retroactively, by the time the facility determines more or fewer staff are needed, the patients are all done and have gone home. The commenter shared that their facility currently has a 1:3 or 3.5 staff to patient ratio and that if a patient is not stable they are sent to the hospital; the facility does not dialyze these patients in the outpatient setting and does not provide acute dialysis. The commenter stated they had examined an acuity-based assessment system which the ANNA has been trying to promote and found little to gain from it for the price. The commenter suggested perhaps the department had been consulting with ANNA.

Response: The department agrees with the commenter that acuity systems for out patient dialysis are not fully developed and functional for staffing projections and has deleted that language from renumbered §117.43(e)(7). The department understands that ANNA is no longer actively marketing their acuity-based assessment system. Comments on the proposed rules were received from ANNA, but there is no consultative relationship between the department and any professional organization, other than the Network MRB.

Comment: Regarding proposed §117.43(e)(5), one commenter stated that a ratio of 4:1 (patient:direct care staff) is good if no problems accrue, such as sickness, machine failure, or emergencies. The commenter expressed that dialysis is a serious business, and should not be treated lightly, and in his experience has led him to feel like "an old car, being taken in to Jiffy Lube for an oil change, pushed through and out!"

Response: The department believes the requirements at §117.43(a) and (b) will provide more personalized care and increase patient involvement in that care. The department has amended the language to clarify that the staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift at the rule renumbered as §117.43(e)(7).

Comment: Regarding §117.43(e)(5), one commenter reported that in an outpatient setting such as a dialysis facility, patients are scheduled and chairs assigned far in advance of the patient treatments to provide order and consistency for patients and staff. The commenter indicated that patients can change acuity levels from one treatment to the next, and asked how control can be maintained if, from day to day, facilities would not know how many staff were needed or where a patient would be seated based on an acuity level assigned at each treatment. The commenter continued to state that patients sometimes react negatively to being moved from what they consider their chair, even if only temporarily. The commenter concluded that staffing ratios would better serve the facility and the patient rather than arbitrarily assigned acuity levels.

Response: The department agrees with the commenter that acuity systems for outpatient dialysis are not fully developed and functional for staffing projections and has deleted that language.

Comment: Regarding proposed §§117.43(e)(3) and (5), 117.43(h)(5) and 117.43(i)(5), one commenter requested removal of all staffing ratios and to instead base staffing adequacy on outcomes. One commenter suggested that staffing levels should be left to the discretion of the facility's governing body. Another commenter suggested eliminating the ratios and look at outcomes with decisions made by the medical director and administrator.

Response: As outcome measures are developed, validated, and accepted by the renal community, the department will revisit these rules, with the potential to omit the ratio requirements for facilities that demonstrate excellent outcomes. In response to the second commenter, the facility's governing body should be responsible for determining staffing levels, but the ratios included in these rules are meant to provide minimum levels which the governing body of each facility should use to determine whether additional numbers of personnel are needed to provide adequate care to their population of patients. In response to other comments, the department has amended the language regarding the ratios for licensed staff at §117.43(i)(5) and deleted the ratio for MSWs at renumbered §117.43(e)(7).

Comment: Regarding proposed §117.43(e)(5), one commenter was in favor of one direct care staff member for every four patients on each shift.

Response: The department acknowledges the support and has retained this requirement.

Comment: Regarding §117.43(e)(5), one commenter stated that a ratio of licensed nurses for pediatric patients should be different than those for adult patients.

Response: The department agrees. The rule in renumbered §117.43(e)(7) describes different staffing levels for nurses taking care of pediatric patients.

Comment: Regarding proposed §117.43(e)(7) and (8), one commenter stated that the RN is responsible for the nature and quality of nursing care, for the assessment and care of patients, developing plans of care for patients, implementing plans of care within the dimensions of practice, and monitoring and evaluating care received. The commenter stated that the RN is educated and trained through a complex educational process which includes curricula and practicum to prepare graduates to practice professional nursing, and continued that LVNs and unlicensed staff do not receive this level of training. The commenter stated that the educational process for an LVN or unlicensed staff member is not designed to include the study of complex physiological and disease processes and how these affect patients and outcomes. The commenter added that the curricula of licensed vocational nursing schools and technician training programs focus on data collection, not the interpretation of what the data sets mean in respect to what action the nurse should take, or how it could affect patient outcomes. A second commenter asserted that RNs were not the only persons qualified to assess patients for dialysis. The commenter added that while this is idealistically an excellent thought, the interest of the public may not be served. The commenter continued that given that family members are relied upon to make patient assessments, it is entirely reasonable and logical that highly skilled LVNs be given the same responsibility.

Response: The department agrees that the educational preparation of an RN is needed to assess and manage today's patient in the outpatient setting, and does not believe that family members participating in the care of their relative, with the patient remaining responsible for his or her care, as in home dialysis, is equivalent to being responsible for a facility's entire patient census. However, the language of the rule renumbered as §§117.43(e) (10) was amended to allow the "charge nurse" to begin initial nursing assessments at the patient's first treatment in the facility and require that an RN complete these assessments within the patient's first three treatments.

Comment: Regarding proposed §117.43(e)(7), one commenter objected to the implication that assessments before and after treatments of each patient by a RN, requiring physical, psychological and social assessments which use professional nursing judgement or follow-up, and specific tasks which require professional nursing judgement or intervention, could be delegated. One commenter alleged that requiring an RN perform all assessments before and after treatment will not improve patient outcomes or the quality assurance mechanisms currently in place. One commenter suggested requiring an assessment during each treatment of each patient be completed by an RN, stating one thorough assessment by an RN during each treatment is sufficient, with updates or additional assessments done for unstable patients. The commenter stated this would allow the nurse to spend quality time with the patients in greatest need. One commenter agreed that the nurse should do an assessment on each patient but stated this could be done during

the treatment, as the patients are seen three times a week and the nurses know more about each patient than a nurse in an acute care setting knows after an initial assessment. One commenter stated that an RN assessment before and after treatment is not practical.

Response: The department agrees in part, recognizing a variety of interpretations regarding the term "assessment." The department has also responded to the commenter's concerns that a single RN would not be able to perform meaningful assessments of every patient pre and post dialysis, given that, in some cases, the facility might be staffed with one RN for a shift of 20 or more patients. Therefore, the department has amended the language at renumbered §117.43(e)(9) to allow direct care staff to make evaluations based on the direct care staff member's training and facility policy, with the requirement that an RN make a professional assessment of the patient when indicated by a question of a change in a patient's status or at the patient's request. Additionally, language has been added at §117.44(c)(3) describing an exception to the requirement that only RNs be placed in charge positions. This exception allows a qualified LVN to function as charge during a three year phase-in period for the requirement that the charge nurse be an RN.

Comment: Regarding proposed §117.43(e)(7), one commenter stated that the requirement for an RN to assess patients as part of their treatment should not be delegated to LVNs because LVNs are not covered by a nurse practice act like RNs. The commenter stated that LVNs are allowed to perform procedures for which they have been trained and determined competent by their employer as well as those learned in school; physical assessment is not a part of the vocational nurse curriculum. The commenter added they would not consider the physical assessment of a patient an act they could legally delegate to an LVN. The commenter concluded that to include LVNs in the minimum standard for physical assessment could mean that in a few facilities unqualified people will be legally providing a vital aspect of health care delivery. Another commenter stated the proposal that RNs conduct assessments before and after treatments should be omitted, as a trained experienced LVN can capably perform such assessments and refer to RNs when needed. Six commenters indicated all licensed nurses should be able to conduct assessments before and after treatment with an RN co-signing. Another commenter asked that the language of proposed §117.43(e)(7) be amended to read "an assessment before and after treatment of each patient shall be completed by a licensed nurse."

Response: The department agrees with the commenter in regard to the responsibility of the RN in providing patient assessment and the fact that vocational nursing curricula do not address physical assessment. In the interest of not constructing an impossible situation for what will in some cases be a single RN on duty to oversee the care of many patients, the department has amended the requirement (renumbered §117.43(e)(9)) to require RN assessment whenever there is a question of a change in the patient's status or at the patient's request. The department has also responded to the concerns of other commenters about the increased costs in requiring an RN to be available to the treatment area at all times, and whether there is currently a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules not diminish access to dialysis services or possibly force small businesses to close. Therefore, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: Ten commenters suggested that the language at proposed §117.43(e)(7) include a statement that when an RN was unavailable and with written notification to the department, an assessment before and after treatment of each patient shall be completed by a licensed nurse.

Response: The commenter's suggestion does not explain the purpose or expected outcome of reporting inadequate staffing. The department has, however, amended this requirement in recognition that a single RN could not accomplish meaningful assessments before and after each patient's treatment every shift, be responsible for his or her own patients and assist with administering medications.

Comment: One commenter disagreed with proposed §117.43(e)(7) stating the staff caring for a patient will have competencies documented in what to do and what to report. The commenter recommended that an RN be required to see each patient each treatment to ensure that appropriate care is being administered.

Response: The department agrees with the commenter and has amended the rule renumbered as §117.43(e)(9) to require care givers report any question of a change in the patient's status to the RN who would then be required to assess the patient.

Comment: Regarding proposed §117.43(e)(5) and §117.43(e)(7), seven commenters questioned if the department was recommending that the RN care for four patients and still be accountable for all assessments before and after treatment and questioned whether this was a realistic or safe expectation.

Response: The department has reconsidered this requirement and revised the language of the rule, renumbered §117.43(7) and §117.43(e)(9), to address these concerns.

Comment: Regarding §117.43(e)(7), two commenters requested clarification regarding the data collection for these assessments being done by any member of the direct care staff since according to the Nurse Practice Act, assessments cannot be delegated.

Response: The department acknowledges the Nurse Practice Act does not permit delegation of assessment, but collection of data, such as measurement of blood pressure, is a task which does not require nursing judgement, and may be delegated. Assessment of the data collected does require nursing judgement and cannot be delegated. The language was amended at renumbered §117.43(e)(9).

Comment: Regarding §117.43(e)(7), two commenters expressed concern that technicians are prohibited from conducting patient assessments and alteration of ordered treatment, including shortening of the treatment time and that this conflicts with "each licensed nurse assigned charge..." described in §117.44(c)(2). The commenter asserted that LVNs cannot

perform assessments and cannot alter treatment, so they cannot perform in a charge capacity. The commenter added that it is unrealistic to expect the LVN to function in a charge capacity because the LVN license does not allow for the delegation of duties, which is an integral part of the system as developed. The commenter concluded that dialysis patients continue to become more complex with multiple diseases, and with needs requiring the care an RN is trained to provide.

Response: The department recognizes the limits of LVN training and licensure, however, due to the concerns of other commenters about the increased costs in requiring an RN to be available to the treatment area at all times, and whether there is currently a sufficient supply of qualified RNs to cover all patient shifts in all outpatient dialysis facilities in Texas, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN. The list of prohibited acts at §117.65 has been amended to allow this.

Comment: Regarding proposed §117.43(e)(7), one commenter agreed that any staff member can collect data, but stated that an RN must assess lung sounds since this requires more advanced knowledge, and it is an RN who must substantiate the assessment adequacy before and after treatment.

Response: In response to concerns that a single RN would not realistically be able to conduct meaningful assessments before and after treatment on all patients while caring for his or her own assignment, acting as charge, and giving medications, the requirement renumbered at §117.43(e)(9) was amended to limit the RN assessments to those patients where there was a question of a change in status. The language referring to the direct care giver assessing lung sounds was deleted. Additionally, a three-year phase-in period has been provided in §117.44(c)(3) to allow a qualified LVN to function as a charge nurse during the graduated implementation of the requirement that the charge nurse be an RN.

Comment: One commenter objected to proposed §117.43(e)(7) allowing only RNs to conduct patient assessments because this has never been demonstrated to improve patient outcomes. The commenter added that a recording of patient complaints and physical exams can be done by any member of the direct care staff, so it is meaningless to require only an RN to do it. The commenter asserted that the dialysis person responsible for the treatment must also conduct an assessment in order to initiate treatment and determine ultrafiltration goals and parameters for the treatment they are about to administer.

Response: The department agrees in part that having what may be a single RN in the facility responsible for each patient being assessed before and after each treatment is not realistic, if what is desired is an improvement in the quality of care delivered, and has amended the language renumbered at §117.43(e)(9) accordingly.

Comment: One commenter asked if the requirement at §117.43(g) applied to maintenance technicians.

Response: This requirement would only apply to maintenance technicians if these individuals also deliver direct patient care.

Comment: Regarding §117.43(h)(5), one commenter, referring to the Network's Annual Meeting on April 12, 1996, where a presenter stated many times that the nutritional status of the patient determines life expectancy, asserted that the dietitian to patient ratio should be 1:80 since the quality of life and the quantity of life of patients is based on their nutritional status. Three other commenters expressed support for the recommendations of §117.43(h).

Response: The department agrees with the commenter that nutritional status is critical to a patient's quality and quantity of life. The department recognizes that the commenter's recommendation is consistent with that of the renal dietitian's professional organization's recommendation of 1:100. The requirement at §117.43(h)(5) has been amended to provide a range to allow facilities some flexibility in determining staffing levels. If surveyors or the annual report identify a failure to provide service or adverse patient outcomes related to nutritional services, the facilities can expect the lower limit to be implemented.

Comment: Forty-three commenters supported the recommendation of the Council of Renal Nutrition to add a new subparagraph (G) to §117.43(h)(2), reading "providing ongoing monitoring of subjective and objective data to determine need for timely intervention and follow-up. Measurement criteria include but are not limited to weight changes, blood chemistries, adequacy of dialysis, and medication changes which affect nutritional status and potentially cause adverse nutrient interactions."

Response: The department agrees and has added this language at new §117.43(h)(2)(G).

Comment: Two commenters suggested changing language at §117.43(h)(2)(C) to require dietitians to consider a patient's cultural preferences in recommending therapeutic diets.

Response: The department agrees and has amended the language.

Comment: Regarding §117.43(h)(2)(D), one commenter stated that counseling a patient's family or significant other would not be appropriate in the institutional correctional setting. The commenter stated that the requirement appears to presuppose the patient is living in the community where family or significant other may have responsibility for diet preparation which is not the case in the institutional correctional setting. The commenter continued that when the offender leaves the institution to return to the community the dialysis facility providing community care would be responsible for this requirement as it would be more germane in that circumstance.

Response: The department agrees with the commenter and provided an exception for correctional institutions in §117.43(h)(2)(D).

Comment: One commenter suggested omission of the requirement for initial collection of data to assess nutritional status at §117.43(h)(3), stating that many patients have had dietary intervention prior to starting dialysis, making this requirement a redundant service and unnecessary; the commenter suggested that requiring the comprehensive evaluation to be completed within 30 days would be sufficient.

Response: The department does not agree with the commenter that early contact with the facility's dietitian is not necessary for new patients and has retained the requirement.

Comment: One commenter opposed the use of ratios for dietitians at §117.43(h)(5).

Response: The department disagrees. The ratio requirement was not deleted, but has been amended to allow for flexibility in determining staffing levels. As outcome measures specific to nutrition are developed, validated, and accepted by the renal community, the department will revisit these rules, with the potential to omit these ratio requirements for facilities that demonstrate excellent outcomes.

Comment: Regarding §117.43(h)(5) and §117.43(i)(5), one commenter stated that imposing quotas on dialysis facilities will be detrimental to the industry and cause many facilities to close or sell to large corporate chains, and that facilities should be measured by patient outcomes, not on how many social workers and dietitians are provided. Another commenter requested that the dietitian and social worker ratios be based on outcomes and suggested language for dietitians such as "these facilities shall employ or contract with the dietitian to provide adequate clinical nutrition services to each patient" to be adopted or considered," and for social services language such as "each facility shall employ or contract with social workers to meet the psychosocial needs of patients that they are responsible for." Two commenters expressed support of a dietitian ratio of 1:150 and added that some facilities have clerical assistance for the dietitian, many nursing home patients have an dietitian in that home, and not all dietitians perform duties such as recommending doses of Calcijex and Epogen or conducting kinetic modeling calculations. Two commenters supported the ratio of one dietitian to every 100 patients. One commenter recommended exceptions to ratios for facilities that provide clerical support for dietitians and social workers. One commenter recommended deleting the requirement for a ratio of dietitian to patient and allowing the facility to determine the dietary staffing required to provide clinical nutrition services for each patient. Another commenter reported providing dietitian coverage at one dietitian per 200 patients and stated their facility has been successful at meeting the Network and Medicare criteria for quality of care. Another commenter stated that the acuity of the patient population should be the criteria used when establishing patient to social worker and dietitian ratios. The commenter continued that time management by the individual is the second factor used in determining patient count, and that the dietitian in the commenter's facility is full time, and reviews all the laboratory work for albumin, calcium, iron, parathyroid hormone, phosphorus and nutrition in general, then meets with the physician and makes recommendations based on established clinic protocol. The commenter concluded she is responsible for a census of 120 patients. Another commenter stated dietitians and social workers are professionals who should be allowed to establish their own patient loads.

Response: The department agrees in part. The department agrees that outcomes should be considered and that ratios are important in providing adequate nutritional intervention. The ratio requirements were not deleted from §117.43(h)(5) as there is evidence that suggests the level and availability of dietitian intervention may relate to a patient's nutritional status, and firm data demonstrating the negative effect of low albumin levels on patient survival. The ratio for dietitians was amended to provide a range, effecting greater flexibility in determining staffing levels. Because such hard data is not available in support of the social work ratio, and in response to these and other commenter's concerns regarding the impact the increased costs associated with these rules may have on the delivery and availability of dialysis services, the ratios for social workers were deleted in §117.43(i)(5). As outcome measures specific to nutrition and social services are developed, validated, and accepted by the renal community, the department will revisit these rules, with the potential to omit the dietitian ratio requirement for facilities that demonstrate excellent outcomes.

Comment: Regarding §117.43(h)(5), one commenter endorsed a ratio of one dietitian to every 200 patients to provide nutritional assessment and nutritional counseling, to monitor nutritional care and to recommend necessary changes; other tasks should be left to nurses and physicians. Another commenter strongly supported the ratio of 1:100 and an adjusted portion of dietitian's time be available for additional patients. One commenter stated that the ratio of one dietitian to 100 patients is not appropriate; some dietitians can handle more than this, and some cannot handle this much. The commenter asserted that the rule should simply state what is to be done and when it must be accomplished. Another commenter asserted that the ratio of one dietitian to 100 patients would add $2.74 to the cost of each treatment in their facility. One other commenter suggested the department eliminate the quota of one dietitian for each 100 patients, stating good standard mortality rates (SMRs) can be achieved with staffing ratios different than those in the rules, and mentions one dietitian to every 212 patients. The commenter continued that well dialyzed patients are healthier, eat better and have less health and social problems, requiring less intervention by a dietitian, concluding that ratios also remove innovation in staffing; keep the dietitians, not the quotas. Another commenter opposed the ratio for nutritional services.

Response: The department does not agree with the first commenter, and agrees in part with the second commenter. The department agrees that some facilities may be able to provide adequate nutritional services by using a greater patient to dietitian ratio. The renal community has presented significant evidence of the critical importance of adequate nutrition to patient survival; the largest chain of dialysis providers has aggregate data from many clinics to demonstrate that patients have a greater chance of dying when their albumin levels fall. Dietitians are the primary staff member responsible for assisting patients and families to understand the importance of nutrition in preventing complications, such as malnutrition and life-threatening hyperkalemia. The department questions whether one of the commenters based their cost estimate on an invalid assumption that no dietitian services were being provided to patients at present. The department's research into the costs and reimbursement (composite rate + reimbursement for ancillary services and private pay) available for dialysis services revealed that the costs associated with the dietitian ratio will not significantly impact facility profit margins. In developing the ratios, the department followed the recommendation of national professional organizations to include ratios for dietitians as an assurance that facility management will commit sufficient resources to allow the ac-

complishment of the listed responsibilities for the dietitian. The department agrees there should be some flexibility within the ratio and has added language for this at §117.43(h)(5), and would expect the facility to consider the capabilities of the individual providing service in using the range listed for dietitians. Therefore, the ratio was not deleted but in order to provide greater flexibility to facilities in determining staffing levels, the department has included a range in the dietitian to patient ratio.

Comment: One commenter stated that they understood that the recommendation at §117.43(h)(5) came from the National Kidney Foundation, and questioned the need for the rules to be so specific in this area when patients vary greatly at different times. The commenter indicated compliance will be very costly for facilities without benefit in improved quality. The commenter described that nutritional service at their facility provides initial evaluations by a dietitian and counseling which is followed up on at least a monthly basis. The commenter stated that nurses, physicians, and physician assistants reinforce these dietary restrictions, along with the dietitian and unless there is some evidence that current patient needs in this area are going unmet in any given facility, current Medicare regulations have been adequate. One commenter alleged that there is no evidence that increased staffing or ratios of staff to patients in this area has any influence on patient outcomes; a much better measure of dietary effectiveness would be to monitor outcomes as described in this section; some facilities may not be able to meet the ratios and treatment costs will be increased without benefiting the patient.

Response: The department has acknowledged the source that the proposed ratios for dietitians are based are the recommendations of the National Kidney Foundation, which is the representative professional organization for renal dietitians. The proposed ratios have been amended secondary to public comment. The department agrees that patients vary greatly at different times, and has incorporated standards to require ongoing assessment to assure changes in needs are recognized and addressed. There is no data to support the commenter's suggestion that Medicare regulations have been adequate, as few outcome measures to evaluate the provision of nutritional have been developed, evaluated, or accepted by the renal community. The department has not received any evidence that nutritional service staffing has no influence on patient outcomes.

Comment: In support of §117.43(h)(5), 35 commenters expressed support for the ratio for dietitians, and stated that some in opposition of the ratio are not aware of the renal dietitian's role in the ESRD population. The commenter stated that most dietitians are members of an interdisciplinary group which includes doctors, nurses, dietitians and social workers, which means that if the dietitian finds that a patient's bone disease will worsen due to high phosphorus levels in their blood, the dietitian needs to figure out if that patient might be consuming foods that the patient does not know are high in phosphorus, so that the patient can avoid those foods. The commenter also stated that when a patient is anemic, the dietitian's role is to find out why this patient's iron stores and iron saturations are low which requires time and patient education. The commenters state they have seen patients improve, have fewer complications and hospitalizations when the dietitian spends more time with them.

Response: The department acknowledges the comment, recognizes the extensive education efforts that are made by dietitians in assisting patients to assimilate their dietary restrictions, and has retained the requirement, with amended language to allow greater flexibility for facilities in determining staffing levels.

Comment: Regarding §117.43(h)(5), one commenter stated they only need one dietitian for every 150 patients, and that more patient conferences and audiovisual materials are all that is necessary to get the same outcomes. Another commenter stated they had worked as a dietitian in renal facilities since 1991 with a ratio of one to 200 patients. From personal experience with this ratio, the commenter stated it was very difficult to educate and deliver effective nutrition care due to the required and necessary charting, multiple care plan preparations and meetings, quality management auditing and reporting, and the needed interdisciplinary informal communication. The commenter stated that more time is being spent on "housekeeping" tasks, taking time away from more in-depth evaluation, chart review and more nutrition education. The commenter concluded that investing in more education for patients by allowing more time for it means a better informed patient who learns preventative measures instead of curative, and fewer hospitalizations, and that the requirement at §117.43(h)(5) would be one way to effectively reduce health care costs. Another commenter endorsed the full time equivalent of dietitian's time in §117.43(h)(5). Two commenters supported the requirement and presented information that quality nutrition care improves nutritional status which directly affects mortality and quality of life in dialysis patients. The commenters stated that the challenge to provide optimum nutrition care is mounting as patients with significant co-morbidities and advanced age increase in number and that an adequate staffing ratio is important to meet this challenge, and to provide preventive care rather than focusing on crisis intervention. The commenters also mentioned a recent study which indicated a need for a ratio better than one dietitian per 157 patients because patients are older, sicker and have higher mortality. The commenters continued that while there is little published data on optimum staffing ratios for renal dietitians, the Council on Renal Nutrition of the National Kidney Foundation has published guidelines for estimating renal staffing levels that, when used to project staffing needs, often produce a ratio of one dietitian for every 100-125 patients. Ten commenters suggested that the language be amended to require each facility employ or contract with a dietitian(s) to provide adequate clinical nutrition services for each patient. Two commenters recommended the requirement at §117.43(h)(5) not be greater that 100-125 patients per one dietitian and stated that a professional organization's recommendation for 150:1 does not take into account quality assurance and quality improvement activities and time, monitoring and follow-up of adequacy of dialysis, monitoring of iron levels, and bone density parameters, all tasks done by dietitians in many facilities. One of these commenters added that, given the serious nutritional problems confronting the dialysis population, any ratio greater than 1:100-125 leaves little time for proper evaluation of patient needs on an individual basis.

Response: The department agrees in part, recognizing the varied and important role that dietitians play in the management of renal patients. A ratio for dietitians was retained at

§117.43(h)(5), but was amended to provide greater flexibility for facilities in determining staffing levels.

Comment: In recommending deletion of §117.43(h)(5), one commenter alleged that because adequacy of dialysis is used as an indicator to verify if the patient's dialysis needs are being met, when the patient's adequacy goals are achieved, the dietitian has met the needs of the patient population.

Response: While the department is aware that some calculations for dialysis adequacy require consideration of a nutritional measure (protein catabolic rate), the department does not agree that having a patient meet a dialysis adequacy goal is a complete measure of whether the dietitian has met the nutritional needs of that patient. The department is willing to revisit the requirement for this ratio when outcome measures specific to the provision of nutritional services are developed, validated, and accepted by the renal community.

Comment: Regarding §117.43(h)(5), four commenters supported the 100 patients to one dietitian ratio. Three of these commenters considered 100 to 125 patients to one dietitian an acceptable ratio for situations where the census fluctuates. One commenter recommended one dietitian to every 200 patients. Another commenter recommended to eliminate ratios and look at outcomes, leaving the decision of staffing levels to the medical director and the administrator. Another commenter expressed support of a ratio of 150 patients to one dietitian. Fifteen other commenters expressed support for particular dietitian to patient ratios; one commenter wanted 1:150-200; four wanted 1:100-125; and 10 wanted 1:100.

Response: The department does not agree, but has amended the language at §117.43(h)(5) to provide facilities with greater flexibility in determining staffing levels. The department is willing to revisit the requirement for this ratio when outcome measures specific to the provision of nutritional services are developed, validated, and accepted by the renal community.

Comment: Regarding §117.43(h)(5), one commenter provided the information that all dialysis patients in the correctional system are concentrated at one location, where they are available on an "as needed" basis for dietary intervention, and that the requirements for dietary intervention in the prison system do not require a ratio of 1:100.

Response: The department appreciates the information about this unique dialysis facility. This ratio has been amended to provide greater flexibility.

Comment: Regarding §117.43(h)(5), one commenter submitted that a ratio of one dietitian to 150 patients is sufficient if dietitians are limited to nutritional assessment, nutritional recommendations, nutritional counseling, and monitoring of nutritional care and are not expected to include adequacy of dialysis or evaluate Epogen or iron regimens. One commenter stated the ratio for dietitians is too restrictive, and proposed that 1:150 is adequate, with 1:175-200 adequate in some areas. The commenter requested the department change this requirement to 1:150-200 based on facility need. One other commenter supported a dietitian ratio of one dietitian per 80-100 patients for pediatric facilities. Another commenter supported the ratio of one dietitian per 150 patients, stating that this ratio would provide one hour and 10 minutes per patient per month, since some patients refuse service and some require less time.

Response: The department agrees that more time is generally required for all staff members who work with pediatric renal patients, and would expect that the needs of the specific population be addressed by the facility without additional specificity in these rules. The department believes that the level of staffing for nutritional services should be based on patient need, with the ratios set as minimums. The department calls the first commenter's attention to the many comments which describe nutritional practices which are expected to include those items this commenter would exclude. The department does not agree with the math calculation of the last commenter, as 70 minutes times 150 patients would equal 22 eight-hour working days per month, and there is no way to predict which patients might require less time and if patients would refuse service. In response to these and other comments, the department has amended the ratio required in §117.43(h)(5) to include a range to provide some flexibility to facilities in determining staffing levels.

Comment: Regarding §117.43(h)(5), three commenters stated the dietitian must be the renal nutrition instructor.

Response: The department believes the commenters are referring the dialysis technician training program, and has responded to this and other comments to include dietitians as instructors for their area of expertise under §117.62(g).

Comment: Regarding §117.43(h)(5), one commenter stated that each facility should be evaluated for patient acuity and patient mix with factors such as medical condition(s), age, economics, number of non-English speaking patients, and fluid overload, all of which affect albumin levels. The commenter stated that albumins of 3.8 milligrams per dilution is a good marker for nutritional intervention.

Response: The department appreciates this information. Surveyors will review such factors in determining the adequacy of the nutritional service being provided, and the Network MRB may advise the department to add an indicator of quality related to albumin to facilities' annual reports in the future. The department does not believe this language is appropriate for inclusion in the rules.

Comment: Regarding §117.43(h)(5), one commenter stated that not every facility has access to or can contract with dietitians in sufficient numbers to meet the proposed regulations.

Response: The department disagrees. The results of the department's staffing survey did not demonstrate a shortage of dietitians in renal facilities.

Comment: Regarding §117.43(h)(5), one commenter stated that there should be one dietitian to every 100 patients as the profile for renal patients reflects an aging general population and there are many co-morbid conditions and concerns that require additional time to address. The commenter stated that even a skilled dietitian is challenged under these circumstances and to overburden the dietitian is counterproductive. One commenter stated that their patients are receiving good nutritional assessments and the dietitians are able to conduct excellent care conferences and quality patient counseling with two dietitians on staff. Another commenter supported a dietitian to patient ratio of 1:100, because there is ample scientific research document-

ing the negative impact of malnutrition on patient mortality and hospitalization rates. The commenter added that an increased dietitian to patient ratio should allow for more intensive nutritional interventions by the dietitian as well as collaboration with the entire health care team. Another commenter presented evidence from the Texas Dietetic Association demonstrating that medical nutrition therapy provided by a registered and licensed dietitian is cost effective and health effective in the prevention and treatment of disease. The commenter also stated that the data indicates that in health care reform and managed health care, more emphasis is placed on prevention and early intervention because the registered, licensed dietitian has become the key member of the health care team for early identification of patients with likelihood of malnutrition, but intervention requires the cooperation of the whole health care team to evoke effective change.

Response: The department agrees with the commenter who stated the importance of nutrition on patient outcomes and that renal dietitians play a crucial role in the care of ESRD patients. The second commenter did not include the patient census of their facility, so there is no information regarding their current status regarding the requirement at §117.43(h)(5). The requirement at §117.43(h)(5) has been amended to provide greater flexibility for facilities in determining staffing levels.

Comment: Regarding §117.43(h)(6), one commenter stated that it is not necessary to have a dietitian on-site during all scheduled treatments to meet the goals related to proper nutritional care, and that it would be sufficient to have a dietitian available for the required clinical activities such as assessments and reassessments on an as needed basis.

Response: There is no requirement for the dietitian to be on-site during all treatments; §117.43(h)(6) is meant to require that the service will be provided at the dialysis facility when the patient is there for treatment, rather than the patient having to go to another location at a different time.

Comment: Concerning §117.43(i), one commenter stated that the psychosocial evaluation of a patient is an ongoing process and is not limited to a one-time written report.

Response: The department agrees and believes the amended language in §117.43(i) addresses these concerns.

Comment: Regarding §117.43(i) and §117.44(e), one commenter stated that the proposed rules do not provide for hardships or exceptions if good faith and effort has been made to hire qualified staff, specifically MSWs. The commenter indicated that in the Rio Grande Valley, there are approximately 28 MSWs, and in order to comply with the proposed ratios, the dialysis centers in the Valley will have to hire at least ten of these 28 social workers. The commenter expressed concern that given the fact that in a five-county area, there are nine hospitals, 86 home health agencies, six hospices, a Texas Department of Human Services regional office and a state hospital, it would be almost impossible to hire these MSWs. The commenter added that the closest university with an accredited master's level program for social workers is 270 miles away and recommended that the department allow and include BSW's as qualified staff under the direction of an MSW. One commenter asserted that there is an acute shortage of MSWs in Texas. Another commenter stated that few MSWs are willing to spend the amount of time necessary or to devote the required energies to meet multiple social problems that present in a renal failure patient. One commenter stated that it would benefit facilities to be allowed to use a mix of full-time MSWs with BSWs to meet the needs of patients. Another commenter asserted that a BSW can perform the social worker function routinely, referring to an MSW when necessary. Three other commenters stated that facilities could effectively use BSWs under full-time direct supervision of an MSW. One of the commenters added that reimbursement rates allowed under the Medicare program are not keeping pace with inflation as a reason for utilizing BSWs instead of MSWs. One commenter suggested the department look at outcomes of patients and leave the decisions up to the physician and facility administrators.

Response: The department agrees in part. The department disagrees that a shortage of MSWs exists in Texas, noting that there are 11,616 licensed MSW's in Texas, distributed in 179 counties. Further, based upon a staffing survey conducted by the department, of 165 facilities responding, only nine facilities reported that no MSW was employed. The department agrees that it is necessary to devote much time and effort in providing quality social services to renal patients. According to information obtained from the social worker licensing board, there are 77 licensed master social workers in Hidalgo county alone. Further, Pan Am University has begun the accreditation process for a social worker graduate program which will in the future add to the MSW workforce in the South Texas region. However, the department recognizes that there may not currently be a sufficient supply of qualified MSWs to meet the ratio requirement in all outpatient dialysis facilities in Texas, in that all licensed MSWs may not have graduated from accredited schools. The department is also concerned that the implementation of these rules as proposed may diminish access to dialysis services and possibly force small businesses to close. Therefore, the department has deleted the ratio requirement for MSWs, but retained language that the facility employ or contract with a master's level social worker(s) to meet the psychosocial needs of the patients. The department understands the issues related to Medicare reimbursement. The department disagrees that the BSW can adequately perform the social services outlined in §117.43(i)(2). Such responsibilities require the education and training obtained through a masters-level program. The department notes that a facility is not precluded from using BSWs to provide discrete services under the proposed rule language, which does specify those services that an MSW must provide directly. The department disagrees that the services described in §117.43(i) should be delivered by an individual other than an MSW. However, the department also recognizes that some facilities may employ social workers who meet the grandfathering language present in the Medicare Conditions of Coverage and, therefore, the qualifications for the social worker in §117.44(e) were amended to mirror the social worker qualifications requirements in the Medicare Conditions of Coverage for dialysis facilities.

Comment: Regarding §117.43(i) and §117.44(e), one commenter suggested consulting with the Texas Board of Social Worker Examiners to determine what policies are already in place rather than making new ones that may conflict.

Response: The department has consulted with the representatives from the social worker licensing board and has not identified conflicts between the rules.

Comment: Regarding §117.43(i), one commenter suggested using BSWs to supplement MSWs in providing social services to dialysis patients. One commenter stated that an arrangement allowing an MSW to supervise a BSW with 10 years experience while the MSW performs the psychosocial evaluation and long term plans and remains available for counseling and group services works well.

Response: The department agrees that BSWs are a valuable resource in assisting MSWs in providing discrete services in the ESRD setting. Under such an arrangement, the MSW would be required to continue providing the services described in §117.43(i)(2); the rules do not preclude the employment of BSWs by a dialysis facility to provide discrete services.

Comment: Regarding §117.43(i), one commenter suggested differentiating social worker time provided to hemodialysis patients and peritoneal dialysis patients, adding the peritoneal dialysis patients are usually seen less frequently. Another commenter stated that in times of increased admissions, it is difficult to provide adequate social services.

Response: The department believes that a social worker can provide quality social services to both hemodialysis and peritoneal dialysis patients under the language in §117.43(i) and §117.44(e). The language was not changed to differentiate services provided to hemodialysis versus peritoneal dialysis patients. The department recognizes that on occasion, a social worker could get behind on completion of the documentation of the provision of service, but did not consider an occasional problem in completing records as appropriate for inclusion in these rules. Changes to the language in §117.43(i) were made in response to other comments and are addressed elsewhere in this preamble.

Comment: Regarding §117.43(i)(2)(A)-(E), one commenter recommended adding subparagraph (F) to state "participating in continuous quality improvement activities."

Response: The department agrees and has added the new subsection and language suggested.

Comment: Regarding §117.43(i)(2)(E), one commenter stated that while the Texas Department of Criminal Justice social services program would be informed by the health services program at the time of the patient's release from the institution to the community of any special services required by the patient, it should not be the responsibility of the institutional based dialysis clinic to refer a patient for assistance, particularly financial assistance.

Response: The department agrees and has added an exemption for correctional institutions from the requirement at §117.43(i)(2)(E).

Comment: Regarding §117.43(i)(3), one commenter suggested deleting the first sentence and just requiring psychosocial assessments for new patients be completed with 30 days of admission. Two commenters suggested changing the rule to allow two weeks for initial contact and documentation with a new patient. Another commenter stated that initial contact in less than two weeks is frequently impossible, and still another suggested increasing the initial contact time in the rule to 14-21 days to allow for times when the social worker is away from the facility for educational purposes or vacation One commenter suggested increasing the initial contact time in the rule to 15 days. A fifth commenter supported the completion of the initial psychosocial assessment within one month and a sixth recommended requiring initial contact between the social worker and the patient occur within two weeks or six treatments from the patient's admission.

Response: The department agrees that two weeks is reasonable and has amended the language to require initial contact between the social worker and the patient and documentation within two weeks or seven treatments from the patient's admission, whichever occurs later.

Comment: Regarding §117.43(i)(5), one commenter stated that rural areas are more affected by these rules than urban areas. Other commenters stated that requiring a 1:80 ratio of social workers to patients is excessive and that the ratios should be deleted. Additional commenters stated that having 80 to 88 patients has allowed the commenter to become a significant member of the dialysis health care team and to provide predialysis education to new patients, and others supported the 1:80 patient to MSW requirement because without this ratio, the social worker is unable to provide quality patient care to chronically ill patients on an as-needed or contractual basis. Another commenter supported the proposed staffing ratio for patients to social workers and stated that patients will have "real access" to qualified social services. The commenter stated that social workers who advocate for ratios higher than the one proposed are those who serve a facility on a consultative basis. According to the commenter, these social workers are paid by the number of patients they see each month, leading them to support an increased patient load. One commenter stated that MSWs must do more than co-sign psychosocial evaluations and another commenter stated that intervention into the psychosocial problems experienced by dialysis patients requires an experienced MSW as opposed to a BSW as has been suggested by others. One commenter indicated that when BSWs are utilized, MSWs are still required to participate in preparing the care plan. Two commenters stated that facilities opposed to lower staffing ratios, such as the 1:80 staffing for social workers, are more concerned about decreased profit margins than providing quality services.

Response: The department disagrees that rural areas will be most affected by the MSW staffing ratio. The department conducted a staffing survey for which it received 165 responses. Of the 165, nine did not utilize an MSW to provide social services. Of the nine, three were rural locations but not inaccessible to a major metropolitan city. However, the department recognizes that there may not currently be a sufficient supply of qualified MSWs to meet the ratio requirement in all outpatient dialysis facilities in Texas. The department is also concerned that the implementation of these rules as proposed may diminish access to dialysis services and possibly force small businesses to close. Therefore, the department has deleted the ratio requirement for MSWs, retaining language that the facility employ or contract with a master's level social worker(s) to meet the psychosocial needs of the patients. The language in §117.44(e)

requires MSWs or individuals grandfathered in §117.44(e)(2) to deliver psychosocial evaluations and other direct patient services, not co-sign the documentation of another lesser prepared individual.

Comment: Regarding §117.43(i)(5), one commenter expressed that the 1:80 ratio does not guarantee that a social worker will have the time to dedicate to specific problems of patients.

Response: The department disagrees that one MSW could not provide adequate social services to every 80 to 100 patients in many facilities while acknowledging that a facility may require more or less MSW time depending upon the needs of its patient population. In response to other commenters, however, the department has deleted the ratio requirement for MSWs, retaining language that the facility employ or contract with a master's level social worker(s) to meet the psychosocial needs of the patients.

Comment: Regarding §117.43(i)(5) and §117.44(e), one commenter expressed support for the 80 to 1 patient to social worker staffing ratio and the MSW requirement as proposed. The commenter cited a caseload of 108 patients who would be categorized as having a high number of psychosocial needs, and expressed observations of the complex problems that kidney patients experience on a daily basis, and added that such high caseloads have often dictated crisis intervention as the only approach to social work services. The commenter added that patients need education, support, group work, a focus on rehabilitation and a proactive approach, as opposed to a reactive approach used after a problem has led to a crisis. The commenter asserted that a master's level clinician is needed because the dialysis population is increasingly elderly or AIDS afflicted and face a decrease in income as well as housing and transportation difficulties and a loss of emotional and social supports requiring the abilities of a highly educated and trained social worker who is able to work independently. Continuing, the commenter stated that access to social work services is a high priority to patients and mentioned an article co-authored by Dr. Peter Landon, a nephrologist and kidney patient who found that greater than 84% of patients surveyed during a 1993 study rely on a nephrology social worker to assist them with coping strategies, the illness's effect on the family and continuing and returning to family activities; and that 91% believed that access to a nephrology social worker is important. Another commenter stated that a ratio is important in order to provide for patient access to quality services. Another commenter supported the requirement for a master's level social worker in §117.44(e) and the ratio for social workers in §117.43(i)(5), stating that the proposed rules are consistent with federal regulations which require an MSW for employment. The commenter added that there is one exception in the Federal regulations and many providers may be confused about this grandfather clause, which allows for a social worker without an MSW to be employed only if they were employed prior to September of 1976. The commenter stated that these "grandfathered" social workers must have continued supervision by a master's level social worker and this clause was not meant to apply to newly hired employees, adding that the Council of Social Work Education which accredits both master's and bachelor's level programs, asserts that a bachelor's degree in social work is a generalist degree which requires supervision. The master's level program however, trains the social worker to practice autonomously and provides for specialization in clinical practice as well as training a social worker in how to evaluate one's own practice.

Response: The department agrees in part and has retained the MSW requirement in §117.44(e) with an amendment to mirror the Medicare regulation relating to the qualifications of social workers. The department has deleted the ratio in §117.43(i)(5) for the reasons mentioned previously in this preamble and to allow facilities flexibility in planning staffing.

Comment: Regarding §117.43(i)(5) and §117.44(e), one commenter stated that it was not necessary to have a social worker for every 80 patients because most of what social workers are now doing in dialysis facilities is paperwork. The commenter added that paperwork activities do not require a master's degree. One commenter recommended deleting the ratio for MSWs to patients and allowing facilities to determine the full-time equivalents necessary to meet the psychosocial needs of their patients. The commenter added that their facility currently provides social worker coverage at a 1:100 ratio and is successful at meeting the ESRD Network of Texas and Medicare criteria for quality of care. Other commenters recommended that the ratio in §117.43(i)(5) be amended to require one MSW for every 80 to 100 patients or changing the social worker to patient ratio from 1:80 to 1:100. One commenter stated that the 1:80 ratio is "out of balance," adding that the social worker doesn't need that much time. Another commenter stated that their facility has one MSW with secretarial and billing staff assistance for 200 patients and does not feel the MSW is overburdened with this arrangement. One commenter recommended changing the ratio to require one social worker for every 150 patients with a two-week turnaround for new admissions and expressed the desire to use clerical staff for the completion of monthly forms. One commenter recommended changing the social worker ratio to require one social worker for every 100 patients. Five commenters supported the ratio in §117.43(i)(5), citing present high caseloads and that MSWs are utilized for crisis intervention or "crisis response" only, and there is no allowance of time for rehabilitation and adjustment counseling, group work and direct services aimed at providing pro-active social services and maximizing the patient's level of functioning. One of the five commenters cited a typical caseload of one social worker per every 120-150 patients. Three commenters supported the proposed 1:80 ratio in §117.43(i)(5) because social workers need the time to provide supportive therapy. Four commenters suggested changing the ratio in §117.43(i)(5) to require one social worker for every 100 patients. One commenter opposed the use of ratios in determining the work load of MSWs, stating that some MSWs can handle more patients and some less. The commenter suggested amending the language to describe what the MSW is to accomplish and when it must be accomplished. Another commenter asserted that requiring one master's level social worker for every 80 patients would add $3.00 to the cost of each treatment. Twenty-nine other commenters supported the 1:80 ratio for master's level social workers. Another commenter expressed support for the ratio of one social worker for every 80 patients, and the ratio should not exceed 100 patients. The commenter expressed concern that many facilities in disagreement with this ratio are basing their position on profit, and may be sacrificing quality of care for increased profit. One commenter supported the ratio

in §117.43(i)(5) because social workers need time to provide counseling to difficult patients, patients with problems such as drug abuse, depression and amputations.

Response: The department agrees in part. The department is concerned to hear from one of the commenters that most of social worker activity in the commenter's dialysis facility is paperwork. Current Medicare Conditions of Coverage require more advanced services be provided and the proposed rule is consistent with the Medicare regulations. Further, the department believes that a reasonable limit for the number of patients per social worker is important to ensure that the social worker is allowed to provide the advanced services necessary to address changes in a patient's self-image, financial security, and role in the community; loss of independence and physical integrity; problems with sexual functioning; and discomfort associated with the chronicity of ESRD. The department agrees that each facility should be responsible for determining the psychosocial needs of its patient population. The department also recognizes that there are increased costs in requiring the ratio and that there may not currently be a sufficient supply of qualified MSWs to meet the ratio requirement in all outpatient dialysis facilities in Texas. In addition, the department is concerned that the increases in costs associated with parts of these rues might diminish access to dialysis services and possibly force small businesses to close. Therefore, the department has deleted the ratio requirement for MSWs, retaining language that a facility employ or contract with a master's level social worker(s) to meet the psychosocial needs of its patients. The rule language in §117.44(e) does not preclude the use of non-MSWs to perform discrete services such as paperwork leaving the MSW free to perform the advanced services. Therefore, the language in §117.44(e) was amended to include the "grandfathering" language of the current Medicare regulations. The use of clerical staff for clerical duties is not prohibited.

Comment: Regarding §117.43(i)(5), one commenter stated that a 1:80 ratio is acceptable as long as an additional social worker is not required until the ratio exceeds one and a half times the original ratio. The commenter added that a "hard and fast" ratio adversely affects small and rural dialysis facilities' ability to attract and keep social workers. Another commenter stated that current practice of using MSW to oversee BSWs has not resulted in any detrimental effects in the commenter's facility which has over 280 patients for 3.5 social workers. Two commenters suggested changing the 1:80 ratio in §117.43(i)(5) to a 1:100 ratio. The commenter stated that retaining the 1:80 ratio would "alienate" dialysis facility administrators from hiring MSWs. Two commenters expressed support of the 1:80 ratio in §117.43(i)(5), stating a higher ratio would result in inadequate patient counseling services and citing older patients and morbidity factors. The commenter also stated that larger caseloads would decrease access to social services for patients and compromise quality of care. Two commenters stated that higher caseloads make it impossible for renal patients to receive high quality or even adequate social work intervention. One commenter stated that their current ratio of 1:120 was too high. one commenter recommended making the ratio 1:125, adding that a ratio is not a job description and others can provide support or clerical services.

Response: The department agrees in part with the commenters and has amended the language as noted in response to other comments.

Comment: Regarding §117.43(i)(5), one commenter stated it was important to have an MSW paired with a BSW to "balance the more educated employees with the more caring" and indicated there were a limited number of MSWs in the commenter's rural area.

Response: The department does not agree with the implication that "more educated" employees are less caring. However, the department understands the difficulties in recruiting master-prepared staff in certain areas of Texas in order to meet the proposed ratios; for this and in response to other concerns of commenters, the ratio requirement in §117.43(i)(5) was deleted.

Comment: Regarding §117.43(i)(5), one commenter stated that for the past ten years, their facility has used a BSW and a consultant MSW.

Response: For 20 years, the Medicare Conditions of Coverage have specified an MSW must provide social services, unless the individual providing social service had worked in dialysis as a social worker for one year before 1976. The department accepts that a BSW can assist an MSW in providing services to patients as long as the BSW's tasks are to provide discrete services. In §117.44(e), the rules require the MSW to provide direct service to all patients. The department has changed the language in §117.43(i)(5) and §117.44(e) as noted previously in response to other comments.

Comment: One commenter supported the proposed social worker to patient ratio of 1:80 in §117.43(i)(5) stating that considering the chronicity of the disease, the aging factor, and the complex psychosocial needs of this population, the lower ratio would allow social workers more time to provide supportive services aimed at increasing a patient's ability to adjust to their illness and reach their maximum potential. The commenter continued that those who advocate for higher staffing ratios are not necessarily focused on patient care, but are more concerned about the profit margin. The commenter quoted the president of the National Council of Nephrology Social Workers who stated "ESRD treatment is not merely intended to extend life, but to extend meaningful quality of life." The commenter asserted that with the psychosocial implications of developing renal failure, access to a qualified social worker would increase by establishing appropriate staffing ratios, and an 80 to one staffing ratio would allow the social worker to focus more on rehabilitation, group work and direct services aimed at maximizing the patient's level of functioning. One commenter opposed a specified number of patients per every MSW because productivity varies among social workers. The commenter recommended amending the language to create a "window" of 80 to 100 patents for every social worker and the use of a second social worker with the BSW degree working under the supervision of an MSW. One commenter stated that the ratio of MSWs to patients to 1:100 was sufficient.

Response: The department acknowledges the comments and agrees that the social worker is an important component in the provision of quality dialysis services. However, the ratio was deleted from §117.43(i) for the reasons mentioned previously in this preamble.

Comment: Regarding §117.43(i)(5), one commenter opposed the staffing ratio of 1:80. The commenter stated that there is sufficient evidence to suggest that the ratio will not affect patient outcomes and that there is a place in the dialysis facility for BSWs. Another commenter suggested the department consider allowing the use of BSWs into the ratio of social workers to patients. The commenter stated that a BSW is trained and qualified to meet the basic needs of the patient, and that providing resources for patients is not the role of the MSW.

Response: The department does not agree that the staffing ratios preclude BSWs from serving dialysis patients in a dialysis facilities or that requiring the use of MSWs does not affect patient outcomes. The training and education of an MSW is important in addressing the changes in a patient's self-image, financial security, and role in the community; loss of independence and physical integrity; problems with sexual functioning; and discomfort associated with the chronicity of ESRD. The language does not preclude the use of BSWs in providing discrete services. The ratios were deleted, however, in response to other comments.

Comment: Regarding §117.43(i)(5) and §117.44(e), 35 commenters expressed support for the ratio of one MSW for every 80 patients, citing that the responsibilities listed in §117.43(i)(2)(A)-(E) are very demanding of time, energy and thinking processes. The commenters added that patients, old and new, need counseling, affirmation and assurance towards acceptance and equilibrium, social functioning and rehabilitation. One commenter expressed support for a ratio of one social worker for every 80 to 100 patients. The commenter stated that many renal companies use only one social worker visit per month which puts the responsibility of providing social services on the nurses, and many administrators are too far removed from direct care to be able to see the difference the ratio could make except for the cost-savings resulting from higher ratios.

Response: The department agrees in part. The department has expanded the MSW requirement in §117.44(e) by adding new language taken from the current Medicare definition of "social worker," and has deleted the ratio in §117.43(i)(5) for the reasons presented earlier in this preamble and to provide facilities greater flexibility in determining staffing levels

Comment: Two commenters disputed the claim of some that there are not enough MSWs in Texas to be able to meet the staffing ratio in §117.43(i)(5) and the qualification requirement in §117.44(e). One commenter added that there are approximately 8,400 licensed master level social workers in Texas and one commenter stated that there were seven graduate schools for social work in Texas, three of these are new, and four of the seven graduate about 700 MSWs per year.

Response: The department agrees that the numbers indicate there are sufficient social workers to provide services to facilities; however, the department believes that there are areas in Texas which may not have a sufficient number of qualified social workers to meet the ratio described in §117.43(i)(5). For this reason, and because of concerns that the increased costs of the ratios might force smaller, isolated facilities to close, the department has deleted the ratio and expanded the qualifications in §117.44(e) to mirror the Medicare Conditions of Coverage.

Comment: Regarding §117.43(i)(5), one commenter stated that facilities did not need more that one MSW per roughly 150 to 160 patients, and that the ratios should be less exact. The commenter stated that the money to be spent on MSWs in order to meet the proposed rule could be used more wisely to extend the treatment time for dialysis patients, and that facilities that have 47% of their patients working full-time do not need to have as many social workers as a facility which receives all of its patients from the county hospital but needs to stay open later and open earlier. The commenter added that rather than trying to "micro manage," the department should establish strict guidelines and expected outcomes and give facilities some flexibility. One commenter supported the staffing ratio of one social worker to every 80 patients, adding that the lower the ratio, the more individual care an MSW will be able to provide to the patient which results in fewer problems and better care. One commenter asserted that if all patients were in one facility, then one social worker can easily provide service to 100 patients and requested revision of the proposed rule.

Response: The department agrees in part. The ratio was deleted for the reasons noted in response to other comments. As outcome measures for social services are developed, validated, and accepted by the renal community, the department will revisit the need for a ratio.

Comment: Regarding §117.43(i)(5), 10 commenters suggested changing the language to require each facility employ or contract with a social worker(s) to meet the psychosocial needs of the patients. One commenter supported the proposed ratio of one social worker per 80 patients, adding that in East Texas, the present caseload is 150, with dialysis patients and transplant patients in addition to pre-transplant psychosocial assessments and requests to initiate referrals. Two commenters supported the ratio of one social worker for every 80 patients. One commenter stated that a realistic and practical rule concerning the role of the MSW for dialysis treatment would be to remove or raise the patient ratio to 1:100 or 130 patients. Another commenter opposed the proposed ratio of one social worker for every 80 patients. One commenter stated that a more realistic ratio is one social worker for every 125 patients, and another stated that a more realistic ratio is one social worker for every 100 or 125 patients. One commenter asserted that the proposed staffing ratios will not improve patient outcomes and suggested monitoring the outcomes of patients instead of imposing ratios.

Response: The department agrees in part. The ratio for social workers was deleted as noted in response to other commenters. These rules do not address the care provided to transplant patients or to pre-renal failure patients. As additional outcome measures for social services are developed, validated, and accepted by the renal community, the department will revisit these rules.

Comment: Regarding §117.43(j)(1), one commenter suggested that the department consider changing "medical director" to "medical advisor" and acknowledge in the regulations the responsibilities of the supervising nurse to which most of the responsibilities are often delegated by the medical director. The commenter stated that the designated medical director does not actually direct the medical care delivered to patients; rather

such direction is done by the members of the medical staff for their respective patients.

Response: The department disagrees to change the terminology from "medical director" to "medical advisor" because the medical director maintains responsibility for developing facility treatment goals, assuring training of nurses and dialysis technicians, monitoring patients and the dialysis process, and developing and implementing all required policies. These responsibilities reflect the role of a "director." Therefore, the department has retained the terminology. The paragraph was reworded for grammatical consistency.

Comment: Concerning §117.43(j)(2), two commenters supported the biweekly physician visits. One commenter added that for two years he never saw a physician, then only for a short visit; and that when there is a problem, it is never solved because the physician is out of town.

Response: The department appreciates the commenter's support and has retained the bi-weekly visit requirement.

Comment: Regarding §117.43(j)(2)(B), one commenter suggested that the description of a pediatric patient be lowered to 14 years of age, adding that many pediatricians have turned the care of adolescents over to adult medicine due to their size, that family practitioners care for children as well as adults, and that adult nephrologists have cared for 14-year-olds without compromise in care for years. One commenter supported the regular input of a pediatric nephrologist for patients who do not live near major pediatric centers. One commenter considered the requirements for consultation with a pediatric nephrologist as unnecessary and stated that the department should not require this. Two commenters requested that adolescents through age 18 and up to age 21 if the patient is still in school and dependent on parental household be seen regularly at a pediatric nephrology center to assist local facilities with special, often unrecognized problems typical of this age group. The commenter added that pediatric centers may also offer special assistance to adolescents who are poorly grown, developmentally delayed or who have a rare pediatric renal disease such as cystinosis.

Response: The department disagrees that an individual of 14 to 18 years of age has matured to adult status and believes that a pediatric nephrologist should be consulted for individuals 18 years of age and younger to address or identify any developmental issues (physical and psychosocial). The department agrees that special attention should be given to adolescents who experience the problems described by the last two commenters. The department disagrees that the age limit should be expanded beyond age 18. Therefore, no change was made to the language.

Comment: Regarding §117.43(j)(2)(B), three commenters supported requiring that pediatric patients, including teenagers, receive care at a pediatric dialysis facility so that this population's special developmental needs can be met.

Response: The department appreciates the commenter's support; the requirement is that consultation with a pediatric nephrologist be utilized and an RN with pediatric experience direct the nursing care of the patient, not that pediatric patients only be accepted by pediatric dialysis facilities. The department has not changed the language.

Comment: Regarding §117.43(j)(2)(B), one commenter suggested allowing direct patient evaluations for pediatrics be completed by "telehealth."

Response: The rules do not preclude the practice of telehealth for this purpose. The department does not believe it is necessary to specify telehealth services are acceptable and has not changed the language.

Comment: Regarding §117.43(j)(2)(B), two commenters expressed support that the care of the pediatric patient be monitored as stated by the rule by a pediatric nephrologist. Another commenter supported the proposed rule relating to the care of a dialysis patient when a pediatric nephrologist is not available as the primary physician.

Response: The department acknowledges the commenters' support and has not changed the language.

Comment: Regarding §117.43(j)(2)(B)(iii) one commenter suggested changing the semiannual direct patient evaluation by a pediatric nephrologist for patients 13 to 18 years of age to an annual direct patient evaluation. The commenter stated that the rule imposes a hardship on the pediatric patient and their families to travel to the pediatric nephrologist

Response: The department disagrees. This language was developed by the Network MRB which includes both pediatric and adult nephrologists. While recognizing that the rule may require some travel on the part of pediatric patients and their families, the department believes this rule will ensure direction of care of the pediatric patient to include planning for developmental as well as medical needs. The language was not changed.

Comment: Regarding §117.43(j)(2)(C), four commenters supported the requirement that each patient is seen by a physician on the medical staff once every two weeks. Another commenter expressed support that each patient receiving dialysis be seen by a physician on the medical staff once every two weeks. The commenter asked how the department will monitor compliance, whether physician payments will be withheld for missed visits and whether patients or staff are supposed to report offending physicians. Another commenter expressed support for the requirement that each patient be seen by a physician a minimum of every two weeks. The commenter stated that achieving acceptable patient outcomes requires the active participation and interaction of the entire health care team of which the physician is the team leader. The commenter also cited articles written by Gordon Lore for the February 1996 issue of "Contemporary Dialysis and Nephrology" and by Emil Paganini, M.D. for the April 1996 issue of "Nephrology News and Issues."

Response: The department appreciates the support and has retained the requirement. Facility compliance will be monitored through the regular survey and complaint investigation process. The department has no authority to withhold physician payments or to regulate physician practice. There is no requirement for patients or staff to report physicians who do not follow the requirement, however, the department would treat such a report as a complaint against the facility. If a violation of the rule is found during a survey or complaint investigation, the facility will be cited appropriately and will be responsible for correcting the violation.

Comment: Regarding §117.43(j)(2)(C), one commenter suggested adding a statement which would ensure every peritoneal dialysis patient is seen by a physician at least once per month. A second commenter identified a requirement at §117.43(k)(2)(C) that home patients have clinic visits quarterly, and suggested that home patients be seen by a physician at least quarterly to agree with the clinic visit requirement.

Response: The department agrees with the second commenter and has added wording applicable to all home dialysis patients at §117.43(j)(2)(C) to agree with the clinical visit requirement in §117.43(k)(2)(C).

Comment: Regarding §117.43(j)(2)(C), one commenter stated that the physician visit every two weeks may be a problem, especially in rural areas, and suggested monthly visits by a physician.

Response: The department disagrees. The department considered requiring monthly physician visits. The Network MRB recommended that physician visits should be made every two weeks. A recent guideline published by the Renal Physician's Association and the American Society of Nephrology recommended weekly physician visits. The department agrees with the Network MRB recommendation and the language was not changed.

Comment: Regarding §117.43(j)(2)(C), one commenter recommended changing the physician visits from every two weeks to monthly visits. The commenter stated that it should be the prerogative of the physician to determine whether more frequent visits are necessary, and that if poor performance due to lack of physician intervention is found, then a corrective action plan could be proposed by a department surveyor.

Response: The department disagrees. The facility is responsible for assuring the delivery of an acceptable level of medical care. This language provides a minimum standard and was not changed.

Comment: Regarding §117.43(j)(2)(C), one commenter believed the optimal frequency of physician visits should be weekly, and added that the department should not impose any numeric frequency to physician rounds as this is a medical practice issue.

Response: The department disagrees. The department's rule does not regulate physician practice, but facility practice. The department encourages the more frequent visits suggested by the commenter; the rules do not prohibit more stringent practices. The language was not changed.

Comment: Regarding §117.43(j)(2)(C), six commenters supported the requirement that each patient be seen by a physician every two weeks. One of these commenters stated that physicians have recently received an increase in reimbursement in recognition of caring for patients with increasing co-morbid conditions and providing more medical leadership in care planning and team direction. The commenter added that it follows that physicians should be providing more medical leadership in care planning and team direction instead of the "minimal" time often currently spent with patients and/or staff. Another commenter stated that for patients, this requirement will go a long way to make patients more comfortable, and may actually prolong their lives. Another commenter expressed agreement with the requirement that patients be seen by a physician once every two weeks, although once a week is ideal, and definitely not once a month. The commenter stated that the physician is the only staff member who can write an order for a test, x-ray, or medications, and although some orders can be provided over the telephone, nothing can replace an actual physician examination. The commenter added that many patients ask medical questions to staff who are not qualified to respond, that some patients complain they have not seen their physician in months and that some physicians seem not to really care as long as the patient is dialyzing in their facility and someone is paying for it. One commenter expressed support for each patient being seen by a physician once every two weeks, adding that the renal population is an aging, more complex patient population and facilities are seeing increasing patient acuity. Two of the commenters indicated that in order to set treatment goals or direct and monitor patient care the physician needs to have first-hand knowledge of the patient's subjective complaints and objective clinical data. These commenters added that although frequency of physician visits does not always equate with the level of care provided, the quality of medical care is difficult to maintain in the long absence of the physician, that many patients in rural areas have multiple medical problems needing physician attention just like patients in urban areas.

Response: The department appreciates the commenter's support and has retained the language.

Comment: Regarding §117.43(j)(2)(C), one commenter objected to the requirement that each patient be seen by a physician every two weeks, citing a lack of data to support it. The commenter added that such a requirement infringes upon the practice of medicine and some facilities where the physician sees patients once per month have the best mortality rates. The commenter continued that there was no correlation between the number of times a physician sees the patient and the patient's outcome, indicating that the data suggests that the less a physician sees the patient, the better the patient does; and that the requirement will endanger the rural facilities and potentially cause them to close.

Response: The department disagrees that the requirement infringes upon the practice of medicine; the rule addresses facility practice. The commenter did not describe the reasons a rural facility would be caused to close based upon the number of physician visits to patients. The department believes that the rule will benefit patient access to services regardless of the patient's location and therefore did not change it.

Comment: Regarding §117.43(j)(2)(C), 36 commenters stated that a physician's visit every two weeks was not adequate. The commenter indicated that licensing should provide better patient care which would allow the patient to receive more attention from his or her physician.

Response: The department appreciates the commenter's desire to provide quality patient care. The rule does not preclude physicians from seeing patients more often than every two weeks. The department did not change the minimum requirement.

Comment: Regarding §117.43(j)(2)(C), one commenter endorsed the use of telemedicine.

Response: The department agrees that telemedicine is an important tool. The requirement does not preclude the use of telemedicine; therefore the requirement was not changed.

Comment: Regarding §117.43(j)(2)(D), one commenter objected to requiring a physician to respond within 30 minutes and proposed deleting the requirement because it is restrictive, unrealistic and unnecessarily detailed. Another commenter stated that a response time for physicians is not practical in all areas (e.g. rural) of the state. A third commenter opposed the response time requirement because including a specific time would place a legal burden upon physicians and put them at risk for claims if the response time took more than 30 minutes. This, the commenter stated, was regulating the practice of medicine. A fourth commenter recommended the response time requirement be deleted. The commenter stated that their facility arranges emergency coverage through the hospital emergency room where physicians are scheduled full time, and that the facility has no control over the response time for physicians.

Response: In response to this and other comments, the department has deleted the 30-minute response time requirement.

Comment: Regarding §117.43(j)(2)(D), one commenter expressed support that a physician on the medical staff be on call and available 24 hours a day to patients and staff and the 30-minute response time requirement. Two other commenters supported the requirement that a physician must call within 30 minutes as beneficial to patients.

Response: The department appreciates the commenter's support. However, in response to other comments, the language was changed to delete the 30-minute response time.

Comment: Regarding §117.43(j)(2)(F), one commenter supported the use of advanced practice nurses or physician assistants to augment, not substitute for the physician services, contingent upon the individual having the appropriate advanced education preparation as recognized for nurses by the Board of Nurse Examiners and for physician assistants by the Board of Medical Examiners.

Response: The department agrees that advanced practice nurses and physician assistants should not be used to substitute for physician services and should hold these titles in accordance with the rules developed by the Board of Nurse Examiners and the Board of Medical Examiners. To eliminate confusion, the department has deleted the words "to augment physician services" and added definitions for "advanced practice nurse" and "physician assistant" which mirror the corresponding definitions developed by the Board of Nurse Examiners and the Board of Medical Examiners.

Comment: Regarding §117.43(j)(2)(G), one commenter recommended changing the rule language to require yearly medical staff meetings instead of quarterly. Another commenter recommended requiring semiannual physician staff meetings for better total care.

Response: The department has deleted §117.43(j)(2)(G) because the Network Criteria and Standards referenced in §117.41(a) require core staff members to meet monthly as part of the facility's quality assurance activities. The medical director is required to participate as a member of the core staff and is responsible for updating the medical staff on treatment goals and other quality assurance issues.

Comment: Regarding §117.43(j)(2)(G), one commenter recommended subparagraph (G) be deleted as it is more appropriate to include it in the section on quality assurance. One commenter expressed she was unaware of any review of the care a family member received. Another commenter recommended deleting the requirement at §117.43(j)(2)(G) for medical staff meetings and to incorporate this in §117.41, as this activity should remain within the quality assurance process. Another commenter objected to the requirement for quarterly staff meetings, and that even in hospitals mandatory requirements are being reduced and outpatient facilities should be not less than yearly.

Response: The department agrees that the subparagraph should be deleted because the Network Criteria and Standards referenced in §117.41(a) already requires that core staff members participate in quality assurance activities. The medical director is responsible for updating the medical staff on facility treatment goals and other quality assurance issues as a participating core staff member. This involvement should address the second commenter's concern. In addition, the department believes that §117.41(c) and (d) are sufficient to involve the medical director by requiring participation of core staff members in quality management activities and requiring the facility to hold monthly quality management meetings.

Comment: Regarding §117.43(k), one commenter objected to allowing a physician to claim that a patient is a home dialysis or self-care dialysis patient if only partial self-care is taught. The commenter believed that some physicians have done this in order to receive the additional fees home training provides.

Response: The department disagrees that §117.43(k) should address this situation because the department does not regulate reimbursement issues. Therefore, the suggestion was not included.

Comment: Regarding §117.43(k), one commenter recommended the RN trainer make a home visit to evaluate the home treatment environment including cleanliness and storage space, and that prior to home training, the patient and the RN should have a written contract regarding the training.

Response: The department believes that the rule language in §117.43(k)(3)(A)(i) and (ii) are sufficient and has not changed the language. Facilities are free to impose more stringent requirements, and to implement internal policies, such as developing a contract between a potential home patient and the nurse responsible for training.

Comment: Regarding §117.43(k), one commenter stated that the role of the LVN is not well defined in the home training program.

Response: The department does not agree that the role of the LVN should be specified. A facility may use LVNs to assist the qualified RN in providing training for home dialysis; however, the RN remains responsible for the training and for supervising the LVNs. The requirement was not amended to address persons assisting with training.

Comment: Regarding §117.43(k)(1), one commenter recommended allowing the substitution of completion of a recognized training course specific to training patients for home dialysis in lieu of experience.

Response: The department disagrees. In response to comments questioning the availability of such training courses, the department has deleted that language, leaving the requirement for experience.

Comment: Regarding §117.43(k)(1), one commenter stated they were unaware of the availability of a "recognized training course specific to training patients for home dialysis, and asked if the department was mandating that one such center be established and who would do the "recognizing." A second commenter expressed he was unaware of a recognized training course specific to training patients for home dialysis and asked why a dialysis technician should undergo more intensive training than a home patient and a home patient should require a more skilled instructor. The commenter recommended that a nurse or preceptor who is qualified to precept new dialysis technicians should be able to teach home patients.

Response: The department agrees and has deleted the language relating to a recognized training course for home dialysis training and reworded the paragraph for clarity. However, the department has retained the language relating to the home training of patients and the qualifications of the nurse trainer. The department believes that the more skilled instructor for patients will be responsible for their own care without supervision is appropriate.

Comment: Regarding §117.43(k)(1), one commenter requested allowing LVNs to assist in training.

Response: The department does not object to using LVNs to assist the qualified RN in providing training for home dialysis; however, the RN remains responsible for the training and for supervising the LVNs. The language does not preclude such assistance and was not changed.

Comment: Regarding §117.43(k)(1), one commenter suggested changing the language to require the nurse trainer be an RN who has had at least 12 months experience in dialysis, six months being in peritoneal dialysis under the direct supervision of a more experienced RN.

Response: The department disagrees and has retained the 12-month experience requirement, but has deleted the language requiring completion of a recognized training course.

Comment: Regarding §117.43(k)(2)(C), one commenter recommended to require clinic visits include the evaluation of laboratory data and a physical assessment on a monthly basis. The commenter stated that less frequent evaluation would be detrimental to continuity of care and result in delayed intervention and identification of problems.

Response: The department believes that §117.43(k)(2)(A)-(F) sufficiently addresses the commenter's concerns and did not amend the rules as suggested.

Comment: Regarding §117.43(k)(2)(D), two commenters suggested changing the words "referral to" to "communication with."

Response: The department agrees and has changed the language.

Comment: Regarding §117.43(k)(3), one commenter asked if the language as proposed relates to equipment needs and services.

Response: The department believes that the rule language is sufficiently clear that it relates to equipment needs and services.

Comment: Regarding §117.43(k)(3), one commenter objected to having the same requirements for a trainer of peritoneal dialysis patients and hemodialysis patients, stating that the trainers for these modalities may be different individuals. The commenter recommended the trainer for peritoneal dialysis be a nurse who has six months experience in dialysis and a current skills checklist on file at the facility, and added that he knew of no course as described in the rule.

Response: The department disagrees that the nurse trainer of peritoneal dialysis should have less experience than the trainer for hemodialysis. The department agrees with the commenter not to require completion of a training course. Therefore, the rules concerning the nurse qualifications were not changed, but the department has deleted the language concerning the training course. The rules do not prescribe that the nurse trainer must be the same person; facilities may use different individuals qualified to conduct the training.

Comment: Regarding §117.43(k)(3)(B), one commenter suggested including the same language as in §117.43(k)(3)(A)(i) because home assessment is also important for continuous ambulatory peritoneal dialysis patients.

Response: The department disagrees. The department recognizes that under certain conditions a facility may determine it is necessary to inspect the home environment of peritoneal dialysis patients, and the rules do not preclude facilities from adopting such a policy. However, given the differences in system components and complexity of the procedures, the department does not believe it is necessary to require facilities conduct home visits for all peritoneal dialysis patients. Therefore, the language was not changed.

Comment: Regarding §117.44, one commenter expressed that many subsections of this section are overly specific and intrusive.

Response: The department disagrees that the standard is overly intrusive or specific. The department believes that the language in §117.44 is necessary to adequately describe the expected qualifications and orientation of patient care staff.

Comment: Regarding §117.44(a)(1), one commenter expressed that the language in the paragraph was broad and vague, and indicated a written program does not improve upon a personal tour.

Response: The department disagrees with the commenter's implication that a written program is not necessary as such a program is essential in providing current staff with a written reference relating to the facility's expectations and in orienting new staff to the facility. The written program may include a requirement for personal tour of the facility. The language was retained.

Comment: Regarding §117.44(a)(2), (4) and (5), one commenter asked whether these paragraphs included maintenance technicians who do not provide direct patient care.

Response: The language in §117.44(a)(2) specifies "new direct patient care staff," §117.44(a)(4) applies to all dialysis technicians, and §117.44(a)(5) applies only to "each staff member providing direct patient care."

Comment: Regarding §117.44(a)(2), three commenters supported specialized training for staff to address the particular needs of the pediatric or adolescent population.

Response: The department disagrees and has not changed the language; however, there are requirements at §117.43(a) that the needs of the patient population of the facility be addressed, and having pediatric patients in the facility should result in evidence of inservice regarding their particular needs.

Comment: Regarding the orientation periods specified by §117.44(a)(2), one commenter stated that for some, this will be too little, for others too much and suggested allowing facilities to determine how much is enough for their facilities.

Response: The department agrees that individuals have varied orientation needs but believes this rule defines a minimum orientation period and has not changed the language.

Comment: Regarding §117.44(a)(2) and (4), one commenter supported the two-week training program described in paragraph (2), but stated that paragraph (4) should allow RNs and LVNs be given the option of being tested by observation instead of skills testing.

Response: The department acknowledges the support of the two-week training program and expects competency testing to be completed by observation and documented via the competency skills checklist. The department has retained the language.

Comment: Regarding §117.44(a)(3), one commenter suggested adding "specific to management of ESRD patients" to the end of the sentence.

Response: The department agrees and has made the change.

Comment: One commenter recommended changing the language in §117.44(a)(3) to require the six-week orientation program for RNs to "be appropriate to the population served by the facility..." in order to ensure the needs of pediatric patients are met.

Response: The department agrees and has amended the language.

Comment: Regarding §117.44(a)(3), one commenter objected to the six-week training of RNs described. The commenter stated that in order to treat a dialysis patient, the nurse has no need to know about Fabrey's disease, renal tubular acidosis or many other kidney diseases, or nor does the nurse need to be "burdened" with the details of management of membranous nephropathy or Barters syndrome.

Response: The department disagrees that the subject content described in §117.44(3) is not important to the nurse in understanding more about the needs of dialysis patients. The language was not changed.

Comment: Regarding §117.44(a)(3)(A)-(J), one commenter recommended that the nursing orientation content include not only the content listed in subparagraphs (A) - (J), but also the subject content described in §117.62(b)(1).

Response: The department disagrees; the basic education of licensed nurses includes the curriculum described in §117.62(b)(1). The language was not changed as suggested.

Comment: Regarding §117.44(a)(4), one commenter supported demonstration of competency through written and skills testing.

Response: The department appreciates the support and has retained the language.

Comment: Regarding §117.44(a)(4), one commenter stated that testing should be done every two years, not annually. One commenter expressed that the need to pass a written competency test annually has no meaning, adding that the ongoing education programs and clinical planning sessions will identify those who need help.

Response: In the interest of patient health and safety, the department disagrees that skills testing in the dialysis setting should be reduced to every two years. The language was not changed.

Comment: Regarding §117.44(a)(4), one commenter recommended that the language be changed to allow nursing managers and staff to determine what high risk, low frequency tasks need to be re-evaluated annually, and what tasks should be evaluated at orientation and again if problems occur for the individual staff members.

Response: The department disagrees. What the commenter suggests could result in more frequent evaluations than the annual required by these rules. A facility may require a more stringent evaluation policy than is described in the rule. The language was not changed.

Comment: Regarding §117.44(a)(4), one commenter asked how the testing will be standardized, where will the tests come from, and what will be the content of the tests. The commenter indicated that unless testing is standardized, then this requirement will discriminate against nurses and technicians across the state, and recommended that the paragraph be amended to require an annual evaluation of the nurse or technician be on file at the facility and should include the components listed in §§117.44(a)(3)(A)-(J), 117.62(b)(1)(C)-(F), 117.62(b)(2), 117.62(b)(3)(D) and (E), 117.62(b)(3)(G)-(K), 117.62(b)(4)(A)-(H), 117.62(b)(5)(C) and (D), 117.62(b)(6)(C) and (D), 117.62(b)(7)(B), 117.62(b)(8)(A), 117.62(b)(9)(A), (B) and (D), and 117.62(b)(10)(A)-(C).

Response: The department does not believe it is necessary to prescribe a standardized test and does not agree with the commenter's statement regarding discrimination against nurses and technicians. The suggested addition of an annual evaluation could be the annual retesting required by §117.44(a)(4). No change was made to the paragraph.

Comment: Regarding §117.44(a)(5), one commenter recommended to increase annual continuing education hours from five hours to 12 hours of education related to ESRD. Regarding §117.44(b), one commenter suggested mandating the medical

director to attend 20 hours of ESRD-related continuing medical education per year.

Response: The department based the requirement for five hours on input from the various professional disciplines in the renal community who requested that this requirement not conflict with their different licensing requirements for continuing education and has retained the language.

Comment: Regarding §117.44(b)(4), one commenter stated that if advanced practice nurses or physician assistants are used, they should be certified or licensed, not just trained by the physician.

Response: The department agrees with the commenter's concept to require certification or licensure, and has added definitions for "advanced practice nurse" and "physician assistant" in §117.2 to describe the meanings of these terms and include that the individual be qualified according to the relevant professional board, and amended §117.44(b) accordingly.

Comment: Regarding §117.44(c), one commenter recommended "grandfathering" of LVNs and allowing two to three years for LVNs to obtain their RN credentials. Two commenters requested that §117.44(c)(2) be rewritten to require the charge nurse be an RN or LVN with two years experience. Two commenters proposed that facilities be able to use LVNs as charge nurses or "grandfather" them in. Four other commenters stated that facilities should be able to use LVNs as charge nurses. One commenter questioned whether an LVN could assume charge nurse responsibilities, particularly when an RN is required to be present at all times in the facility. Another commenter alleged the proposed regulation requiring charge nurses to be RNs is not only appropriate but well over due. Another commenter asked if an LVN could function as a charge nurse, and another commenter expressed that an LVN with experience of one year should be allowed to take charge in the absence of an RN, as these individuals do provide evaluation of patients in settings where the dialysis community always has a severe shortage of RNs available for hire.

Response: The department agrees in part. Under the proposed language, any LVN would have been able to function in the charge role. However, the language in §117.44(c)(2) was amended to require the charge nurse to be an RN. The department also amended §117.44(c)(3) to create an exception allowing the charge nurse be an LVN. Under the exception, the LVN charge nurse must be employed in a facility as of September 1, 1996, and have two years experience as a charge nurse in a facility prior to September 1, 1996. The exception expires on September 1, 1999. During the three-year period this exception is in effect, the department will collect data through the survey and complaint investigation process to determine whether the exception affects patient events or outcomes. In regard to the shortage of RNs for hire in dialysis, a department staffing survey demonstrated that the primary areas where patient shifts were not covered by RNs were Houston, San Antonio, Austin, Corpus Christi, and Beaumont. Each of these cities includes or is near a university or college which offers an RN program. The hospitals in these cities are undergoing redesign of the work force, and RNs are frequently displaced during such efforts, increasing the supply of nurses available for hire by dialysis facilities. The language in proposed §117.44(c)(3) was renumbered as §117.44(c)(4).

Comment: Regarding §117.44(c)(2), 10 commenters recommended that each licensed nurse assigned charge responsibilities have six months experience in hemodialysis obtained within the last 24 months or when unavailable and with written notification to the department, each licensed nurse assigned charge responsibilities shall have less than six months experience in hemodialysis. Another commenter stated that only RNs are assigned charge responsibilities at their facility and when trained some have demonstrated readiness after six months but some have not. The commenter suggested changing the language to require orientation to charge with documentation of competency assessment.

Response: The department disagrees and has not changed the language as suggested. However, the department has changed the language to require charge nurses be RNs, added language to describe the charge nurse's responsibilities and to allow certification in nephrology nursing or hemodialysis substitute for the experience. The department has also added language in §117.44(c)(3) to provide an exception that an LVN employed in a facility on September 1, 1996, and who has two years of experience as charge nurse prior to September 1, 1996, may serve as a charge nurse until September 1, 1999. This three-year phase-in period will allow the department to collect data as previously mentioned in this preamble. The department does not agree that it is necessary to mandate orientation on charge duties in the rules. This does not preclude a facility to require such an orientation as facility policy.

Comment: Regarding §117.44(c)(2), one commenter objected to restricting charge nurse responsibilities to nurses with six months experience within the last 24 months.

Response: The department disagrees and has retained the experience requirement. The department has changed the qualification to require a charge nurse be an RN with the exception for an LVN to function as charge as noted in response to previous comments.

Comment: Regarding §117.44(c)(2), one commenter asked how an LVN can function as charge when they are prohibited in §117.65(a) from performing two basic functions of a charge nurse-patient assessment and alteration of ordered treatment.

Response: The department agrees in part and has changed the language to require the nurse assigned charge responsibilities be an RN with the LVN exception noted in response to other comments. The language in §117.65(a) was amended to be consistent with this exception.

Comment: Regarding §117.44(c)(3), one commenter stated that an RN with six months experience is sufficient; the 12 months of experience is not necessary.

Response: The department disagrees that six months experience is sufficient for training others in self-care dialysis. Therefore, the 12-month experience requirement was retained.

Comment: Regarding §117.44(c)(3), one commenter supported the requirement that the RN trainer of self-care have 12 months experience obtained within the last 24 months.

Response: The department agrees in part. The rule language requiring the RN have at least 12 months experience was retained; the language requiring that this experience be obtained within the last 24 months was deleted.

Comment: Regarding §117.44(d), one commenter recommended adding language requiring that each dietitian is licensed in Texas and registered by the Commission on Dietetic Registration and expressed a preference for at least one year of clinical nutrition experience and previous renal nutrition experience.

Response: The department agrees in part. The department is not in a position to endorse a private organization such as the American Dietetic Association's Commission on Dietetic Registration (ADA/CDR) as suggested. However, the department has changed the language to require eligibility for registration by the ADA/CDR, and to require the dietitian to have accrued one year of experience in clinical dietetics after becoming eligible for registration.

Comment: Regarding §117.44(d), one commenter stated that dietitians should be registered.

Response: The department is not in a position to endorse a private organization such as the ADA/CDR as suggested. However, the department has changed the language to require eligibility for registration by the ADA/CDR, and to require the dietitian to accrue one year of experience in clinical dietetics after becoming eligible for registration.

Comment: One commenter requested an additional two years of clinical nutrition experience in §117.44(d) instead of one year of experience.

Response: The department does not agree that two years of clinical nutrition experience should be a minimum requirement and has retained the requirement for one year's clinical experience obtained after the individual becomes eligible for registration. A facility may require more stringent qualifications for its nutritional staff than the minimum qualifications described in §117.44(d).

Comment: Regarding §117.44(d), eight commenters supported the requirement that dietitians be licensed and eligible for registration.

Response: The department appreciates the commenters' support, and has added clarifying language to identify the ADA/CDR as the entity which approves registration.

Comment: Regarding §117.44(d), one commenter opposed the requirement that dietitians be eligible for registration because it was redundant and not necessary.

Response: The department disagrees that eligibility for registration by the ADA/CDR is not an important indicator of competency in determining whether a dietitian is qualified to provide the specialized services needed by ESRD patients. The additional experience and education necessary to obtain eligibility for registration better prepares the renal dietitian to work in the dialysis setting. The rule was not changed as suggested.

Comment: Regarding §117.44(e), one commenter asserted that an MSWs training provides skills necessary to work autonomously, think analytically, and self-evaluate performance. The BSWs training and education is task-oriented.

Response: The department acknowledges the comment and has retained the qualification requirement in §117.44(e) and the definition of "social worker" in §117.2 with a modification to be consistent with the definition of "social worker" in the Medicare Conditions of Coverage.

Comment: Regarding §117.44(e), one commenter indicated that an MSW is necessary in order to meet the increasing expectation that the ESRD health care team focus on patient rehabilitation and quality of life issues

Response: The department agrees and has retained the language.

Comment: Regarding §117.44(e), two commenters stated that an MSW is needed because facilities are providing services to older and sicker patients who may have even more individualized and complex psychosocial needs.

Response: The department agrees that older and sicker patients require special consideration in dialysis. The department also believes that every individual receiving dialysis services may have special needs requiring the support of an MSW. Therefore, the language was not changed except for consistency with Medicare regulations.

Comment: Regarding §117.44(e), one commenter cited the need for an MSW exists because the AIDS virus may affect the psychosocial needs of some dialysis patients.

Response: The department agrees that dialysis patients with the AIDS virus may require special consideration by an MSW. The department also believes that every individual receiving dialysis services may have special needs requiring the support of an MSW. Therefore, the language was not changed except for consistency with Medicare regulations.

Comment: Regarding §117.44(e), two commenters stated that an MSW should be required because the complex psychosocial issues cannot be adequately addressed by non-MSW staff and to address the needs of multi-problem patients who may also be illiterate or who require financial assistance in order to receive dialysis. Another commenter asserted that the MSW has more formal training and experience in dealing with the social service needs of dialysis patients than do BSWs. Another commenter stated that the MSW is required to address the needs of multicultural patients.

Response: The department agrees that individuals who are not master-prepared social workers have not received the education and training needed to address the complex psychosocial issues related to dialysis. Therefore, the department has retained the language as proposed, except that language mirroring the Medicare regulations was added for consistency.

Comment: Regarding §117.44(e), one commenter requested the use of a bachelor's prepared social worker in conjunction with a master's level social worker. The commenter stated that the bachelor prepared social worker is trained in and the best person to meet the basic needs of the patient, that providing resources for our patient population is not what the master's level social worker should be doing. The commenter continued that therapeutic intervention is what the master's level social

worker is trained to do and is not what is most needed by a patient and that restricting a facility by requiring a social worker be a person who holds a master's degree discounts the skills and training of a bachelor's level worker.

Response: The department disagrees that the rule should be changed as suggested. The training and education of an MSW is important in addressing the changes in a patient's self-image, financial security, and role in the community; loss of independence and physical integrity; problems with sexual functioning; and discomfort associated with the chronicity of ESRD. In addition, the rule language does not preclude the use of BSWs to provide discrete services in ESRD facilities. The staffing survey conducted by the department identified only nine facilities, of the 165 that responded, that did not have an MSW on staff. Information obtained from the social worker licensing program supports there is an adequate supply of MSWs available in the state. The department believes that the rule should mirror the current Medicare regulation related to the qualifications of a social worker and has changed the language in §117.44(e) and in the definition of "social worker" in §117.2 to that effect.

Comment: Regarding §117.44(e), one commenter stated that facilities which assert that MSWs are unavailable or cost-prohibitive to use are offering salaries appropriate for an entry-level BSW.

Response: The department acknowledges the comment.

Comment: Regarding §117.44(e), one commenter stated that the use of MSWs will contribute to the desired goal to keep patients alive longer which in turn will increase profits by not reducing patient census. One commenter asserted that the MSW is crucial to provide social services in a dialysis facility to promote quality of life in addition to the other needs of the dialysis patient; four others supported the MSW requirement as the appropriate qualification for providing social services to dialysis patients. Another commenter stated that an MSW is needed to meet the expectations of patients to assist them with coping strategies for ESRD. A fourth commenter stated that the MSW requirement is effective in achieving measurable outcomes. Another commenter stated that the MSW is important to be effective against the high rate of depression reported in hemodialysis patients, and since cognitive depression is an important predictor of mortality in patients with ESRD, the MSW's advanced education and experience is needed. Another commenter supporting the MSW requirement asserted that dialysis patients experience more complex medical and psychosocial dilemmas (e.g., declining physical and emotional capabilities, losses of emotional and social support systems, increasing occurrence of dementia, and income, housing and transportation difficulties). The commenter added that in 1991, 45% of new patients were over 65 with 17% over 75. One commenter supported the MSW requirement and added that BSWs are trained in general social work practice and relegated to work under supervision in contrast to autonomously.

Response: The department agrees that the goal of providing quality social services contributes to desirable outcomes for dialysis patients. For this reason, the department has not changed the language except as noted in response to other comments.

Comment: Regarding §117.44(e), two commenters supported the MSW requirement as a component of achieving optimal care for the dialysis patient. A third commenter asserted that the MSW requirement is very important in providing quality dialysis services to patients. Another commenter supported the MSW requirement because the use of BSWs attempts to manipulate the Medicare regulations and causes confusion in defining the BSW's role as well as decreasing the ability to establish a trusting relationship with the patient. The commenter added that building a trusting relationship with a patient is key to provide comprehensive psychosocial services. One commenter supported the requirement for MSWs, citing reasons to include changes in a patient's self-image, financial security, and role in the community; loss of independence and physical integrity; problems with sexual functioning; and discomfort associated with the chronicity of ESRD.

Response: The department agrees and has retained the language, except as noted in response to other comments.

Comment: Regarding §117.44(e), one commenter asked the department to recognize that persons other than MSWs can perform some social services such as clerical, transportation, transient arrangements and referrals.

Response: The department recognizes that others can provide the discrete services cited by the commenter. Because the rule language does not preclude the provision of such services by others, the department has retained it except where changes were made for consistency with Medicare regulations.

Comment: Regarding §117.44(e), one commenter stated that the requirement does not address the use of a social worker with a BSW who has been working under the close supervision of an MSW. The commenter added that prohibiting such an arrangement could prove a hardship in very rural areas.

Response: The rule language does not preclude the arrangement described by the commenter, with the MSW responsible for providing direct service to all patients. No change was made to the language, except as noted in response to other comments.

Comment: Regarding §117.44(e), one commenter stated that the MSW requirement is not justifiable from a patient care or financial standpoint. The commenter added that at a minimum, existing BSWs should be "grandfathered" because many facilities will not be able to meet the requirements.

Response: The department disagrees. The training and education of an MSW is important in addressing the changes in a patient's self-image, financial security, and role in the community; loss of independence and physical integrity; problems with sexual functioning; and discomfort associated with the chronicity of ESRD. In addition, the rule language does not preclude the use of BSWs to provide discrete services in ESRD facilities and is consistent with the Medicare Conditions of Coverage for ESRD Facilities. The staffing survey conducted by the department identified only nine facilities, of the 165 that responded, that did not have an MSW on staff. Information obtained from the social worker licensing program supports there is an adequate supply of MSWs available in the state. Therefore, the language was not changed, except as noted in response to other comments.

Comment: Regarding §117.44(e), two commenters asserted that a BSW working under the supervision of an MSW can provide sufficient care for patients, adding that it would be a disservice to the commenters' facilities to lose experienced BSWs because of this rule. Another commenter stated that BSWs are competent in finding resources in the community, making referrals, offering encouragement and support as long as there is quarterly documentation of MSW consultation. A third commenter stated that the MSWs are not available in rural East Texas and assumed that the rule excludes the use of BSWs in rural facilities. The commenter stated that MSWs are contracted to sign patients up for benefits and be on call for crisis intervention.

Response: The department disagrees that the rule excludes the use of BSWs. The rules do require an MSW to provide direct services to each patient, not merely co-sign notes by other workers at some later date. This requirement is consistent with the Medicare Conditions of Coverage for ESRD, and reflects a belief that the training and education of an MSW is important in addressing the changes in a patient's self-image, financial security, and role in the community; loss of independence and physical integrity; problems with sexual functioning; and discomfort associated with the chronicity of ESRD. The rule language does not preclude the use of BSWs to provide discrete services in ESRD facilities. A staffing survey conducted by the department determined that out of 165 respondents, only nine did not have an MSW providing social services, of which three could be considered to be in rural areas. Discussions with the social worker licensing program revealed that of the 15,000 social workers in Texas, 60% are licensed master social workers (LMSWs); review of data provided by that program of the number of MSWs by county failed to support the commenter's assertion that MSWs are not available in rural East Texas, for example there are 21 LMSWs in Angelina County, 47 LMSWs in Gregg County, and 27 LMSW's in Nacogdoches County. The language of this requirement was not changed, except for amendments made to maintain consistency with Medicare regulations.

Comment: Regarding §117.44(e), six commenters disputed the average salary for a master's level social worker of $17-$23 per hour quoted by one facility administrator, indicating that the national average of salaries for an MSW is $12-$18.50 per hour.

Response: The department acknowledges the comment and appreciates the information. No change was made as a result of the comment.

Comment: Regarding §117.44(e), 32 commenters supported the requirement that a social worker have an master's degree in social work. Another commenter supported the requirement for MSWs, stating that the master's level social worker has the expertise and education to work with such a complex patient population. The commenter added that the family dynamics and the issues surrounding chronic illness as well as death and dying are too complex for bachelor's level social workers.

Response: The department agrees and not changed the qualification in §117.44(e) or the definition of "social worker" in §117.2, except to be consistent with Medicare regulations.

Comment: Regarding §117.44(e), one commenter proposed broadening the requirement that a social worker be an MSW to allow an individual without an MSW degree to work as a social worker as long as the individual has served at least two years as a social worker prior to September 1, 1996, one year of which must have been in a dialysis or transplantation program. The commenter's suggestion cited the lack of MSWs in certain markets as reason to amend the language. Another commenter stated that requiring an MSW will have a significant negative impact on the delivery of social services to renal failure patients, and another stated that requiring only MSWs could result in a deficit of services to renal patients. The commenter added that there is a place for the BSW in the care of renal patients. Another commenter stated that BSWs provide quick and sound judgement in the provision of social services.

Response: The department disagrees that MSWs should not be required to provide advanced social services and agrees that BSWs may provide quality discrete services. A staffing survey conducted by the department determined that out of 165 respondents, only nine did not have an MSW providing social services. Discussions with the social worker licensing program revealed that of the 15,000 social workers in Texas, 60% are licensed master social workers (LMSWs); review of data provided by that program of the number of LMSWs by county failed to support the commenter's assertion related to the market for MSWs. However, because neither this survey nor the data is sufficiently conclusive in negating the commenter's statement, the department added grandfathering language which mirrors the language presently in the Medicare Conditions of Coverage for ESRD facilities.

Comment: Regarding §117.44(e), one commenter indicated that MSWs are scarce in Amarillo and suggested allowing facilities to use a person to assist with social work and complete paper work who is a college graduate and who works under the supervision of an MSW. The commenter expressed concern than under the proposed language, patients would lose the services of the non-MSW, costs would increase and the new MSW would not perform as well. Another commenter expressed concern that West Texas does not have an MSW program to provide MSWs to that part of Texas. One commenter stated that their facility has advertised for two weeks in Lubbock for a qualified social worker with no response. Another commenter stated that masters prepared social workers are difficult to find in El Paso and this difficulty is augmented by the need to hire Spanish speaking MSWs with experience in providing care to dialysis patients. The commenter asked if BSWs could be used under these circumstances

Response: The department disagrees that the proposed rule would eliminate the use of non-MSW staff as these persons are not precluded from performing the discrete services mentioned by the commenter. Regarding the perceived scarcity of MSWs, the social worker licensing board reports there are 11,616 LMSWs in Texas, with 55 in Randall County and 65 in Potter County. In addition, the social worker licensing program reports that the University of Texas at Arlington does provide MSW courses in El Paso. The rules do not preclude a BSW from assisting the MSW through the provision of translation services. To maintain greater consistency with Medicare regulations, the department amended the rule.

Comment: Regarding §117.44(e), one commenter stated that requiring additional academic credentials for social workers

in ESRD in order to provide basic essential services would be a giant step in the wrong direction. Another commenter expressed that requiring the social worker be an MSW is unrealistic. A third commenter stated that requiring MSWs will increase costs and result in a decrease in staff and the level of quality of care.

Response: The department disagrees. An MSW prepared social worker has been required in the Medicare Conditions of Coverage since the inception of the ESRD program. The department believes that non-MSW individuals do not have the education or training to provide the advanced social services needed by patients who require dialysis. The department further disagrees that the quality of care will decrease as a result of requiring MSWs. Continuing the present requirement for these services to be performed by adequately qualified staff is a step in the right direction for ESRD patients. The language was not changed except as previously noted.

Comment: Regarding §117.44(e), one commenter stated that a licensed social worker supervising another, even non-degreed individual, can more than adequately address and resolve patients needs. Another commenter supported the use of MSWs adding that with a good assistant, an MSW can do what he or she is trained to do best-enhance the ESRD patients' lives. One commenter stated that patients receive better quality services and more continuity of care when utilizing MSWs with BSWs. One commenter stated that in 22 years of providing dialysis services, the commenter's facility has never had an "acceptable" MSW for longer than a few months.

Response: The department agrees that an MSW can supervise a non-degreed individual to perform paperwork activities and that a trained and qualified social worker is important in improving the quality of care provided to a dialysis patient. The rule language does not prohibit the use of a social worker assistant or other qualified individual to assist the MSW in the provision of social services. However, the department disagrees that the services described in §117.43(i) can be performed by a non-degreed individual. Therefore, the department has not changed the language, except to be consistent with Medicare regulations.

Comment: Regarding §117.44(e), one commenter stated that in the Rio Grande Valley there are approximately 28 MSWs, that the dialysis facilities there would have to hire at least 10 additional MSWs to comply with the proposed rules, and the commenter's facility utilizes one MSW and four BSWs to care for 320 patients.

Response: The department does not believe that one MSW can perform the advanced social services described in §117.43(i)(2) for 320 patients, and reminds the commenter that the current Medicare regulations also require the MSW provide these services. The department accepts the use of BSWs to provide discrete social services to assist MSWs. The social worker licensing program reports that the counties of Hidalgo, Cameron and Willacy are home to 141 LMSWs. There are 379 LMSWs living south of San Antonio, from Corpus Christi to the Rio Grande. In order to maintain consistency with the Medicare regulations, the department amended the language.

Comment: Regarding §117.44(e), one commenter requested exceptions be granted to the MSW requirement or to continue with the HCFA "waiver," especially in rural areas and other areas where there is a shortage of MSWs.

Response: The department has expanded the definition at §117.2 and the rule at §117.44(e) to include the "grandfather" clause included in the Medicare Conditions of Coverage requirement for MSWs. This clause allows persons who were providing social work services for two years before 1976, with one year as a social worker in an ESRD facility, to work as a social worker with a consultative relationship with a MSW.

Comment: Regarding §117.44(e) and §117.43(i), one commenter recommended that the staffing ratios be dropped and that BSWs be included as qualified social workers. Another commenter expressed that a BSW is qualified to provide many basic services including transportation, food, shelter, program applications, community referrals and education. The commenter added that an MSW is needed to provide more extensive services such as psychosocial assessment, care planning and counseling and can be provided through a consultative arrangement.

Response: The department disagrees that the MSW requirement should be deleted and BSWs should be included in the description of qualified social worker, but agrees to delete the staffing ratios for the reasons noted previously in this preamble. The social worker is responsible for providing the advanced social services described in §117.43(i)(2). A BSW does not have the education or training to provide these services. The rules do allow facilities to utilize BSWs and others in the provision of discrete services as described by the second commenter. Therefore, the department has not changed the language, except as previously noted.

Comment: Concerning §117.44(e), one commenter asked the department to detail the circumstances under which a BSW can render services.

Response: The BSW can provide discrete services to patients such as arranging transportation, taking care of paperwork, telephone referrals and assisting in completing financial assistance applications. The BSW may not perform the duties described in §117.43(i)(2).

Comment: Regarding §117.44(e), one commenter stated that a "degreed person" should not have to complete transportation arrangements. The commenter added that 40% of the work is paperwork which does not need to be completed by a "degreed person."

Response: The department agrees that the handling of transportation requests and routine paperwork does not require completion by a "degreed person." The rules do not preclude non-degreed staff members from providing these discrete services, and therefore the department did not change the language, except to maintain consistency with Medicare regulations.

Comment: Regarding §117.44(e), one commenter stated that patients feel confusion as to "who is caring for me" when BSWs are utilized to provide social services. One commenter stated that the use of BSWs to provide social services compromises the continuity of care provided to patients.

Response: The department acknowledges the comment; language in these rules does not prohibit the use of assistants to

perform some of the discrete social services such as arranging transportation, or assistance in completing forms. The MSW will be expected to provide, at a minimum, the more advanced social services in accordance with the rule. The rule language was amended, however, to mirror the social worker qualifications presently in the Medicare regulations for ESRD facilities.

Comment: Regarding §117.44(e), three commenters objected to the use of consultant MSWs by facilities because such consultants have no knowledge of ESRD and that such MSWs do not know the patients.

Response: The department disagrees that all consultant MSWs lack knowledge to provide social services in the ESRD setting or the ability to understand the facility's patients. No changes were made to the rule except to maintain consistency with Medicare regulations.

Comment: Regarding §117.44(e), one commenter supported the use of MSWs in dialysis facilities, adding that formal training and experience allows the MSW to work in the holistic approach to assist the ESRD client in dealing with physical, social and psychological issues related to ESRD. The commenter stated that many times the "noncompliant" patient is an expression of the patient's difficulties in adjusting to dialysis.

Response: The department agrees that the MSW's training and education is essential in meeting the psychosocial needs of the dialysis patient and has retained the MSW requirement.

Comment: Regarding §117.45, one commenter stated that most dialysis facilities perform bone density, nerve conductance and cardiograms and that reporting these test results to the patient should follow a formalized reporting protocol to insure patient receipt of test results.

Response: The department agrees that these test results should be communicated with the patient. However, the department believes that this communication is best accomplished during the physician's routine visits with the patient or unscheduled visits at the patient's request. The language was not changed, except as noted in response to other comments.

Comment: Regarding §117.45(a)(2), one commenter stated that clarification was necessary as to whether it is acceptable to store records on company property in another facility or designated location.

Response: The department agrees that clarification is needed regarding the storage location of the medical record, and has added language in §117.45(a)(2) to be clear that active clinical records be stored on-site on the facility premises, and in §117.45(a)(6) to be clear that inactive records may be stored in an off-site location as long as security is maintained and the records are made available for review by department survey staff.

Comment: Regarding §117.45(a)(2), one commenter agreed a place for clinical record storage is necessary, but stated that additional space for dictating, sorting, recording or reviewing records is not necessary.

Response: The department agrees with the commenter and has amended the language to require sufficient space to store records and accommodate any other activities for which the room is used, such as sorting or reviewing records.

Comment: Regarding §117.45(a)(5), one commenter asked if the practice of computer charting of progress notes is allowed under the rules concerning clinical records.

Response: The practice of computer charting does not conflict with the language in §117.45(a)(5) if signature stamps are not employed, the computer system contains adequate safeguards to assure the information is authentic and protected from casual access, and, if the facility policy requires a hard copy be maintained, the computer generated progress notes are incorporated into the clinical record in a timely manner.

Comment: One commenter stated that their hospital-based facility is installing a paperless record-keeping system and expressed concern that this paperless system would be compatible with the licensing rule in §117.45(a)(5).

Response: The department cannot determine from the information provided by the commenter whether the paperless system being installed will be in compliance with §117.45(a)(5). The language in §117.45(a)(5) does not prohibit the use of an integrated computer system to store records for hospital-based facility patients and inpatients of the hospital. The requirement relates to a security system to protect the clinical records against unauthorized use and inappropriate amendments.

Comment: Regarding §117.45(a)(7), one commenter stated that the clinical record for pediatric patients should contain the growth chart and immunization record.

Response: The department agrees that such information should be contained in the clinical record for pediatric patients; however, the department believes the requirement that the record contain a history and physical for each patient is sufficiently prescriptive.

Comment: One commenter stated that §117.45(a)(7) should include a record of infections as a component of each patient's clinical record.

Response: The department agrees that a record of infections is an important component of a patient's clinical record. This information, however, should be reflected in the physician's or nurse's progress notes, physician's orders, problem list, diagnostic studies, patient care plan, and laboratory reports. The department believes that a requirement for a separate infection record for each patient is not necessary and has not specified it in §117.45(a)(7).

Comment: Regarding §117.45(a)(7), one commenter stated the clinical record should include detailed training sections with documentation of the patient's or assistant's competency.

Response: The department agrees that the records of patients who are trained in self care and home treatment should reflect the training provided and the demonstration of competency by the patient and their assistant and believes §117.45(a)(7)(P) is sufficient to require this documentation. The language was not changed.

Comment: One commenter suggested changing §117.45(a)(7)(O) to read "patient care plans, including evidence of team review and adjustment."

Response: The department agrees and has made the change.

Comment: Regarding §117.45(b), one commenter indicated that home patients needed to have the yearly physical examination performed by the primary care nephrologist rather than allow the nephrologist to use a history and physical done by another physician when the patient underwent a surgical procedure or other hospital care. The commenter added that these histories and physicals are not as informative about the patient's needs for dialysis as those performed by a nephrologist.

Response: The department disagrees that history and physicals performed by non-nephrologists outside of the dialysis facility will not provide sufficient information to dialysis facility staff. The language in §117.45(b) does not preclude the patient's primary physician in the dialysis facility from obtaining additional information or a reexamination of a patient. The intent of the language in §117.45(b) is to describe acceptable time frames for performing the initial history and physical in order to best assure the health and safety of the patient. The language was not changed as suggested although it was amended to extend the completion time of the history and physical and to clarify that the clinical record must include the base line data mentioned.

Comment: Regarding §117.45(b), one commenter stated that a history and physical are usually performed in the physician's private office or at a hospital. The commenter added that if the history and physical is performed in a hospital, the facility or facility physician has no control of the examination procedure and recommended that the examination be performed in the dialysis facility within 30 days from the patient's admission. The commenter further recommended that in the interim, the facility should receive data which includes the patient's reason for ESRD, co-morbid illnesses, current medications, laboratory values, and active medical problems.

Response: The department agrees in part and has amended the language to require that prior to the patient's first treatment, the physician must inform the charge nurse of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. However, the department believes that flexibility should be given to facility physicians regarding the time lines for a history and physical. Therefore, the department has changed the language in §117.45(b) to require the history and physical be performed 30 days prior to or within two weeks after admission to the facility. This change allows a facility physician to perform a history and physical during the physician's first visit to the patient in the facility, or to accept a history and physical performed by a physician outside the dialysis facility.

Comment: One commenter recommended that documentation of progress notes in §117.45(c) correspond with the frequency of physician contact.

Response: The department believes that progress notes should be made whenever the patient assessment or treatment change, and to document the ongoing care of the patient. The frequency of these entries would vary with the individual patient with entries being required at a minimum of every six months. The text in §117.43(j)(2)(C) requires physician visits at least once every two weeks; the physician may want to document his visit, but might not need to make a progress note with each visit.

Comment: Regarding §117.45(d), one commenter expected medication changes and physician orders to appear on the patient's daily treatment record. The commenter further stated that §117.45 gives the facility too much room for putting off catching up on the record keeping, adding that if there were a requirement prohibiting the facility from billing for services until patient records were updated, facilities would do a better job on keeping these records current.

Response: The department agrees that changes in medication and physician orders should be a part of the patient's clinical record and that clinical records be kept current. The department believes this requirement is clear in §117.45(a)(7)(C) and (H). Surveyors report that it is difficult to locate the current treatment orders when orders are recorded on the daily treatment records rather than on an ongoing order sheet. The department does not have statutory authority to prohibit facilities for billing a third party (e.g., Medicare or private insurance) for services when the facility is deficient in updating a clinical record, and has not included such a prohibition.

Comment: One commenter, referencing §117.45(e), stated that there was no medical reason to obtain monthly screening laboratory results relating to a transient patient's hepatitis B status if the patient will be dialyzing in the facility for less than 30 days. The commenter added that the patient's home dialysis facility should provide the hepatitis B status to the transient dialysis facility within 30 days prior to dialyzing in the transient facility, that transfer of the home facility's care plan for the patient is not necessary unless the patient will dialyze more than 30 days in the transient facility, and that care plans, screening labs and hepatitis B status in the transient dialysis facility be required for transient patients dialyzing in the transient facility more than 30 days.

Response: Regarding the need to obtain hepatitis screening on transient patients, the requirements at §117.34(d)(2)(C)(iv)(I) - (III) apply to transient patients as well as to routinely admitted patients. The department agrees that communication should exist between the home facility and the transient facility, and believes §117.45(e) reflects the minimum information to be communicated in order to provide safe dialysis, both for transient and regular patients.

Comment: Regarding §117.45(f), one commenter recommended that this subsection be amended to read, "Clinical records shall be completed within 30 days after discharge. The discharge summary shall clearly identify the disposition of the patient and shall include the diagnosis at discharge or cause of death, date of discharge or death, location of death, transplant or relocation information when appropriate, and reason for discharge, if not transplantation or death."

Response: The department agrees and has amended the subsection.

Comment: Regarding §117.45(h), one commenter stated that it was necessary to transfer records to another outpatient dialysis facility when a patient is transferred, but questioned the reasonableness for transferring records to a hospital since the patient's nephrologist at the dialysis facility is the admitting physician for the hospital.

Response: The department disagrees that it is less necessary to transfer clinical record information if the receiving facility is a hospital. The transfer of certain clinical record information

is important in assuring continuity of quality patient care. The department has deleted the requirement to transfer progress notes, and clarified the language to specify what records would need to be sent whenever a patient is transferred elsewhere for dialysis.

Comment: Regarding §117.45(h), one commenter stated that the interdisciplinary notes are a relevant component of a patient's clinical record when the patient is transferred to another outpatient dialysis facility, but not to a hospital.

Response: The department agrees and has deleted the requirement to transfer the most current progress note from each member of the interdisciplinary team when the patient is transferred to a hospital.

Comment: One commenter stated that the 10-year storage of clinical records in §117.45(i) is too long and suggested changing the requirement to a five-year retention period.

Response: The department agrees and has changed §117.45(i) to require original records be retained for a period of five years.

Comment: Regarding Subchapter E, four commenters expressed support for the language relating to dialysis technicians.

Response: The department appreciates the support.

Comment: Regarding §117.61(c), one commenter expressed that he had no objection to requiring an LVN and a dialysis technician to work under the supervision of an RN or that an LVN or dialysis technician undergo a longer training program than an RN. The commenter stated, however, that an LVN's education, skills and privileges differ the LVN from the dialysis technician, implying an objection to the inclusion of LVNs in the rules relating to training and competency evaluation for dialysis technicians.

Response: The department agrees that by successfully completing the required education and clinical experience necessary to obtain licensure in vocational nursing, the LVN is a valuable component to the dialysis nursing team. The department is restricted by the statutory definition of a dialysis technician which includes LVNs (by virtue of not exempting the LVN with physicians and registered nurses). Under this restriction, the LVN must undergo the same training and competency evaluation as unlicensed individuals working in the capacity of a dialysis technician. The department's rules relating to the training and competency evaluation of dialysis technicians do not preclude an LVN from performing the nursing duties allowed under the LVN license. Additionally, the department has added an exception to §117.44(c) to allow an LVN with two years experience as a charge nurse in a dialysis facility to continue to function as a charge nurse until September 1, 1999, providing a phase-in period for the requirement that a charge nurse be an RN.

Comment: Regarding §117.62, one commenter stated that all dialysis technicians, not just patient care technicians should be trained in patient care and that equipment technicians should be more than just "qualified to perform their duties."

Response: The department agrees that training all dialysis technicians (not just the patient care technicians) on patient care would provide reuse and mechanical technicians with increased knowledge in performing their duties. However, the department believes facilities should retain the authority to decide whether a technician who does not perform patient care duties should be required to undergo the patient care curriculum. A facility may impose stricter standards for its patient care staff than the rules describe; each facility may require all technicians to be trained and tested under the same curriculum if it opts to do so.

Comment: Regarding §117.62(a)-(c), two commenters stated that dialysis technician modules should meet the ANNA guidelines for the delegation of responsibilities to ensure safety.

Response: The department disagrees because ANNA has not developed guidelines for dialysis technician training. The commenter may be referring to an ANNA position paper on delegation, and if so, that position paper was considered in developing the curricula in §117.62(a)-(c).

Comment: Regarding §117.62(b), one commenter recommended that the department require all technicians take a course in aseptic procedures.

Response: The department agrees that aseptic procedures should be taught to the dialysis technician; §117.62(b)(9)(B) already requires the curriculum content for dialysis technicians include infection control and safety measures, specifically universal precautions, aseptic technique, sterile technique, and specimen handling. The rule was not changed.

Comment: Regarding §117.62(b), one commenter expressed concern that the training requirements for dialysis technicians are more intensive than those for RNs under §117.44(a)(3), and recommended that the curriculum in §117.62(b) be deleted and replaced with the components described in §117.44(a)(3). The commenter added concern as to whether smaller rural units will be able to meet these requirements.

Response: The department disagrees that the dialysis technician training curriculum should mirror the components of the RN orientation program described in §117.44(a)(3). The patient care technician is an unlicensed individual performing specialized tasks. The technician has had no previous formal training or education in a health related field. The RN has completed course and clinical studies which cover content comparable to many of the components described in §117.62(b). The content which the department believes should be reintroduced to an RN who does not have dialysis experience is listed in the minimum orientation program under §117.44(a)(3).

Comment: Regarding §117.62(b), two commenters stated that the rules should reflect acceptance of the Board of Nephrology Examinations for Nurses and Technicians (BONENT) or National Association of Nephrology Technologists (NANT) certification in lieu of the training and testing described.

Response: While the department is not in a position to specifically endorse private organizations such as BONENT or NANT, the department agrees that certification by such organizations should be considered in the rules. Therefore, the department has amended §117.62(f) and §117.63(b) to allow for substitution of current certification as a dialysis technician by a nationally recognized testing organization for the written examination. Regarding training prior to testing, the department understands that BONENT and NANT require experience in direct patient care in the dialysis setting as a condition to take the BONENT or NANT exam. Because of this experience, under §117.62(i) a certified dialysis technician could participate

in a shortened training program not less than a total of 80 clock hours of combined classroom and clinical training.

Comment: Regarding §117.62(b), one commenter stated that it was unrealistic for the curriculum to be taught in 80 hours of classroom education.

Response: The department agrees that 80 hours of classroom education alone is not sufficient to adequately provide training to a dialysis technician with no previous dialysis experience; therefore, the department is also requiring at least 200 hours of directly supervised clinical training (§117.62(i)). Certain components of the curriculum may be covered in this 200 hours clinical training.

Comment: Regarding §117.62(b), one commenter asked if the Core Curriculum for the Dialysis Technician developed by Amgen, Inc. could be adopted as a training manual.

Response: The department has reviewed the Core Curriculum for the Dialysis Technician developed by Amgen, Inc.; the components of the curriculum specified by these rules that are not included in the Amgen document are §§117.62(b)(1)(C), 117.62(b)(3)(l), 117.62(b)(4)(G), the components "safety" and "quality control" in 117.62(b)(4)(H), 117.62(b)(5)(D), 117.62(b)(8), 117.62(b)(9)(E), and 117.62 (c).

Comment: Regarding §117.62(b)(3), four commenters recommended addressing adolescent growth and development to this paragraph.

Response: The department agrees that adolescent growth should be considered in the provision of services to this age group; however, the department does not believe it is necessary to include such a specialized component in the basic curriculum for the training of dialysis technicians. The rules do not preclude a facility from including the suggested component in its technician training program.

Comment: Regarding §117.62(b)(3)(F), one commenter requested the addition of the phrase "related to age" at the end of this statement because the psychosocial aspects of ESRD are different at various ends of the age spectrum.

Response: The department agrees that age is an important factor in understanding the individual with kidney failure. However, the department believes that the amended language to §117.43(a) which requires each facility to develop policies and procedures appropriate to the population served, and the language in §117.43(b)(2) which requires the facility's interdisciplinary team to develop an individualized care plan is sufficient to address the commenter's concern regarding the age-associated issues of the ESRD patient. The language was not changed as suggested by the commenter.

Comment: Regarding §§117.62(b)(4)(A), (B) and (D) and 117.63(c)(17), one commenter expressed that these requirements addressed activities that patients and patients' families understood erroneously that staff at a dialysis center would automatically perform. The commenter stated that the staff at one center performed none of the activities described in these rules, and advised that making these activities required training is appropriate and necessary.

Response: The department agrees and has not changed these requirements.

Comment: Regarding §117.62(c)(1), one commenter recommended to delete involvement of dialysis technicians in peritoneal dialysis. The commenter added that technician training does not include or provide for continuing patient education and ongoing assessment for possible complications which are significant components of the care and management of peritoneal dialysis.

Response: The department disagrees. The involvement outlined in §117.63(d) represents strict parameters for the technician's role. The care of peritoneal dialysis patients would continue to be primarily provided by RNs.

Comment: Regarding §117.62(f), one commenter stated that the testing for dialysis technicians should be the same as for RNs and that the minimum score of 80% should also be required of RNs. The commenter expressed concern that the 80% score was too high, stating that it is higher than the grade point average needed to obtain an undergraduate degree.

Response: The department disagrees that RNs should complete the same testing as is required for dialysis technicians. An RN has already completed formal studies covering the components described in §117.62(b) and by virtue of receiving a license from the Board of Nurse Examiners (BNE) has successfully passed the BNE's test covering relevant content. The minimum score of 80% is meant to ensure dialysis technicians have incorporated a sufficient amount of their training to deliver safe dialysis care.

Comment: Regarding §§117.62(g)(1) and (2) relating to instructors, 15 commenters stated that each professional discipline should be able to teach dialysis technician trainees on their area of expertise (e.g., dietitian should teach nutrition services, social worker should teach social services).

Response: The department agrees and has added §117.62(g)(3) to allow a qualified dietitian or social worker to provide dialysis technician training within their area of expertise.

Comment: Regarding §117.62(i), one commenter recommended to reduce the training time to 160 hours or four weeks in addition to two weeks of didactic training (resulting in a minimum of six weeks training).

Response: The department disagrees with this commenter, has not changed the language, and would refer this commenter to other comments expressing concern that the specified time period would not be sufficient to accomplish the instruction and clinical practice required to complete the training program outlined.

Comment: Regarding §117.62(i), one commenter suggested that dialysis technician training for patient care should include six to seven weeks of classroom and practical study, with a two-week clinical internship prior to being included in the staffing ratio for direct care staff.

Response: The department agrees and commenter's suggestion is consistent with the rules. In accordance with §117.61(a), an individual may not act as a dialysis technician unless the individual has undergone the training and competency evaluation described in §117.62 and §117.63. Technician trainees may provide patient care only as part of their training program while

under the immediate supervision of a RN or assigned preceptor. Therefore, a dialysis technician trainee may not be counted in the ratio for direct patient care staff.

Comment: Regarding §117.62(g), one commenter recommended allowing a qualified dietitian and social worker to provide training to technicians in the areas of basic renal nutrition, psychosocial aspects, patient rights and rehabilitation.

Response: The department agrees and has added this language at §117.62(g)(3).

Comment: Regarding §117.62(h), 10 commenters recommended that the language be amended to allow a facility to use licensed nurses and patient care technicians who have less than one year experience in hemodialysis if the facility notifies the department that (the currently required) staff are unavailable.

Response: The department disagrees with the commenters' suggestion. The commenter's suggestion does not explain the purpose of reporting inadequate staffing qualifications.

Comment: Regarding §117.62(i), one commenter stated that their facility usually trains one person at a time and suggested that the department consider deleting a set length of training and instead require a demonstration of competency in the required knowledge through written testing and a demonstration of required skills.

Response: The department disagrees. The length of training represents the minimum time necessary to complete the curriculum in §117.62(b) and (c) in order to demonstrate competency and pass a written test. The facility may require additional time for their technician trainees when indicated.

Comment: Regarding §117.62(i), one commenter stated that the length of training for dialysis technicians should definitely have at least 200 hours of training which is directly supervised.

Response: The department agrees with the commenter and has retained the requirements for 80 clock hours of classroom and 200 clock hours of clinical training.

Comment: Regarding §117.62(i), 10 commenters recommended that a facility should be able to reduce the length of training provided to its technician trainees if the length of training specified in the rule was "unavailable" and the facility provided written notice to the department.

Response: The department disagrees with the commenters' suggestion. The commenter's suggestion does not explain the purpose or meaning of reporting an "unavailable" length of training or in reporting inadequately prepared staff.

Comment: Regarding §117.62(i), one commenter expressed confusion as to what would be considered prior dialysis experience. The commenter stated that if the technician was trained and employed in dialysis for six months, the commenter believed this six months to mean prior experience. The commenter added that if, after 80 hours of classroom orientation and competency verification, there are questions about the technician's qualifications, the facility could require the 200 hours of supervised clinical training.

Response: The department agrees with the commenter's interpretation of the rule language.

Comment: Regarding §117.62(i), one commenter asked if RNs are required to complete a six-week orientation, how can the department justify only seven weeks for personnel with no direct patient care experience, especially since these new technicians will be handling medications for the very first time.

Response: The training program for RNs should build on the professional education that the nurse brings to dialysis. The program should provide information specific to the management of the ESRD patient, training in the technical aspects of the provision of dialysis, and result in competency to provide and direct dialysis service. The training of the dialysis technician focuses on the technical aspects of the provision of dialysis, and basic skills needed to monitor patients under the supervision of an RN. The department reminds the commenter the time frames listed are minimums; some individual technician trainees and some RNs may need longer training periods to achieve competency.

Comment: Regarding §117.63, one commenter stated that technicians use needles in a non-skilled way.

Response: The department acknowledges the comment and has included venipuncture skills in the competency evaluation required at §117.63(e)(1).

Comment: Regarding §117.63(a), one commenter expressed that clarification was needed as to whether the department intends the training review committee to meet each time a trainee has completed the training program. The commenter also opposed the composition of the committee, recommending instead that the nurse manager have sole responsibility for verifying competency of the technician trainee.

Response: The review committee must meet each time a trainee or group of trainees has completed the training program. Requiring a formal system to review completion of orientation is meant to prevent the premature release of orientees from training and provides a forum for the instructor and preceptor to discuss the trainee's competence with a physician. The department believes that because a physician delegates his license to technicians if the physician requests that the technician cannulate access, administer saline, heparin, and lidocaine, the physician must be involved in the technician trainee evaluation process.

Comment: Regarding §117.63(a), one commenter requested clarification of why a committee will determine competency instead of the training instructor and preceptor, adding that the function of technicians is limited.

Response: Requiring a formal system to review completion of orientation is meant to prevent the premature release of orientees from training and provides a forum for the instructor and preceptor to discuss the trainee's competence with a physician. The department believes that because a physician delegates his license to technicians if the physician requests that the technician cannulate access, administer saline, heparin, and lidocaine, the physician must be involved in the technician trainee evaluation process.

Comment: Regarding §117.63(a), one commenter recommended the language be modified to accept BONENT or NANT certification in lieu of testing. The commenter further recommended that instead of a skills checklist, a dialysis technician

should be able to provide proof of five hours of continuing medical education (CME) or continuing education unit (CEU) credits in the field of dialysis.

Response: The department agrees in part. While the department is not in a position to specifically endorse private organizations such as BONENT or NANT, the department agrees that certification by such organizations should be considered in the rules. Therefore, the department has amended §117.62(f) and §117.63(b) to allow for substitution of current certification as a dialysis technician by a nationally recognized testing organization for the written examination. The department disagrees with the commenter to substitute proof of five hours of CME or CEU credits for the skills checklist. Use of the checklist involves the facility in the training and competency evaluation of their dialysis technicians and makes it clear that the facility is responsible for determining their competency.

Comment: Regarding §117.63(a), one commenter asked what constituted a review of records and a validation of successful training, whether the rule requires a formal meeting to review each person trained, and requested the time frame for each review.

Response: The department expects the review of records to include all documents related to the training of the dialysis technician. Examples of such records include any tests, skills checklist(s), instructor and/or preceptor comments regarding the progress of the training and any recommendations from the instructor and/or preceptor concerning the trainee. The rule specifies that a specified group of individuals will meet and review the records; the formality of that meeting would be left to the individual facility. The department does not believe a time frame for such review should be mandated. Each facility may develop a time frame for committee review as part of a review policy.

Comment: Regarding §117.63(c)(10), one commenter asked what prescription other than the patient's dialysis prescription is meant by the rule.

Response: The department agrees that the word "prescriptions" is misleading and has changed the word to "prescription."

Comment: Regarding §117.63(c)(13), one commenter recommended changing the language from "changing patient position" to "placing patient in Trendelenburg position" as this is what the commenter believed was intended.

Response: The department agrees and has changed the language.

Comment: Regarding §117.63(e)(1)(A)-(H), one commenter stated that when a trainee initiates treatment and inserts needles for the first time, the trainee should be supervised one-on-one and not one nurse watching the activities of two or more trainees.

Response: The department agrees and refers the commenter to §117.61(c) which states that a trainee may provide patient care (e.g. cannulation) only as part of the training program and under the immediate supervision of a registered nurse or assigned preceptor. The definition of "supervision" includes a description of "immediate supervision" to mean that the supervisor is actually observing the task or activity as it is performed. Therefore, a trainee must be supervised one-on-one in performing the activities described in §117.63(e)(1)(A)-(H).

Comment: Regarding §117.65(a), several commenters expressed concern that LVNs functioning in charge positions would be prohibited from providing safe care unless some exemptions were made to the list of prohibited acts.

Response: The department agrees that the list of prohibited acts should be amended to allow LVNs to function in charge capacity in a dialysis facility. Therefore, the language in §117.65(a) was amended so that LVNs who function as charge nurses could effectively serve in that capacity to extent afforded under their license. The department recognizes that an RN may not delegate assessment, but believes that an LVN functioning in the charge role must be competent to collect baseline information and to notify an RN or physician if this data indicates a need for referral. The remaining paragraphs under §117.65(a) were renumbered accordingly.

Comment: Regarding §117.65(b), one commenter stated that the section suggests that the department does not believe that technicians and nurses are competent or qualified, care for their patients, and take pride in their professionalism.

Response: The department disagrees. The department recognizes the skills and expertise of qualified staff to perform services in the dialysis facilities. However, the department believes that individuals should not be expected to perform activities outside of the individual's education and training.

Comment: Regarding §117.65(b), one commenter stated that if direct patient care technicians must show proof of competency by exam, why were technicians being more limited by the prohibitions.

Response: The written exam and competency skills check list should test over the required curriculum and listed skills. The items listed as prohibited acts are not included in the curriculum or on the skills list. The statute required that prohibited acts be defined.

Comment: Regarding §117.65(b)(1), one commenter stated that initiation via central catheter is less complicated than cannulating a fistula. The commenter added that technicians can be trained to initiate treatment via central catheter, have been trained, and that the training and skills have been documented. One commenter supported the connection and disconnection of central catheter lines by unlicensed dialysis technicians under the delegation of an RN.

Response: The department disagrees. The potential for patient harm by an individual who does not have the necessary knowledge or education to understand the hazards of working with central catheters precludes the use of these unlicensed individuals from performing this task. The Nurse Practice Act prohibits RNs from delegating invasive, sterile techniques such as central catheter connection/disconnection to unlicensed individuals. Such procedures, if now being practiced, are probably being done via physician delegation.

Comment: Regarding §117.65(b)(1), one commenter stated that it was inappropriate for the department to prohibit dialysis technicians from initiating dialysis via a central catheter because

such a procedure is the "easiest" vascular access that can be done and should be part of the skills required of someone delivering dialysis.

Response: The department agrees that it is easier to connect the blood lines to the ports of the catheter than it is to cannulate an access. However, the potential for immediate and irreversible patient harm by an individual who does not have the necessary knowledge or education to understand the hazards in working with central catheters precludes these unlicensed individuals from performing this task.

Comment: Regarding §117.65(b)(1), one commenter asked the department to consider allowing dialysis patient care technicians to access a patient's central catheter if the technician has a minimum of six months dialysis experience and completion of a training module. A second commenter stated that dialysis technicians should be allowed to initiate a central catheter if an RN assesses the patient during each treatment and is notified of unusual findings. Other commenters stated that the dialysis technician should be allowed to initiate dialysis via central catheter if an RN is in the facility, that properly trained technicians are competent to initiate treatments in this manner, and that prohibiting dialysis technicians from initiating dialysis via a central catheter will result in patients waiting too long for treatment, causing confusion and uproar from patients and decreasing the quality of care.

Response: The department disagrees that a high-risk procedure such as catheter access should be performed by an unlicensed individual. The potential for immediate and irreversible patient harm by an individual who does not have the necessary knowledge or education to understand the hazards in working with central catheters precludes these unlicensed individuals from performing this task. In the interest of patient health and safety, the department has not changed the language.

Comment: Regarding §117.65(b)(1), a commenter supported the language, stating that dialysis technicians do not have the educational background or clinical expertise to work with central lines.

Response: The department appreciates the support and has retained the language.

Comment: Regarding §117.65(b)(1) and (2), one commenter disagrees with the Nurse Practice Act prohibiting an RN to delegate tasks such as initiating dialysis, administering saline, heparin or xylocaine.

Response: The department has no authority to enforce or alter the content of the Nurse Practice Act. The Nurse Practice Act is enforced by the Board of Nurse Examiners and may be amended only through legislative action. The department is obligated to develop and enforce rules which do not conflict with other state laws.

Comment: Regarding §117.65(b)(1), one commenter stated that dialysis technicians should be permitted to initiate dialysis via a central catheter under the delegation of an RN following the successful completion of a training module. Under such a scenario, the commenter stated that the RN would retain responsibility for monitoring the patient and make judgements regarding the access.

Response: The Nurse Practice Act does not allow an RN to delegate sterile or invasive procedures to unlicensed personnel. The department disagrees that a high-risk procedure such as catheter access should be performed by an unlicensed individual. In the interest of patient health and safety, the department has not changed the language.

Comment: Regarding §117.65(b)(2), one commenter supported the rule which allows dialysis technicians to administer normal saline, heparin or lidocaine in course of a routine dialysis treatment. The commenter added that this is the only feasible manner dialysis care can be provided.

Response: The department agrees that safe dialysis is provided by allowing dialysis technicians to administer saline, heparin or lidocaine.

Comment: Regarding §117.65(b)(4), one commenter stated that dialysis technicians should be allowed to perform venipuncture if the technician has a skills checklist on file at the facility.

Response: The department disagrees. Non-access site venipuncture is a technique that a patient care technician does not have the educational background or clinical training to perform. This procedure is infrequently performed in outpatient facilities thus there would be limited opportunity to teach patient care technicians the needed skills, or to have them maintain the skills after being taught. The prohibition was maintained.

Comment: Six commenters supported §117.65(b)(7) requiring the use of RNs and not technicians to care for children younger than 12 years of age or under 30 kilograms.

Response: The department acknowledges the support. However, §117.65(b) which lists acts that are prohibited for dialysis technicians who are not licensed nurses, does not prohibit LVNs from providing care to pediatric patients. Further, the renumbered §117.43(e)(6) does not require an RN to care for the referenced age group, but requires an RN be "available" to provide the care. Also, in response to other commenters who requested the definition of pediatric patients be consistent throughout the standards and commenters who expressed concerns regarding the availability of nurses with pediatric dialysis experience, the department has changed the age and weight requirements in renumbered §117.43(e)(6) and §117.65(b)(7) to 14 years of age and 35 kilograms in weight.

Comment: Regarding §117.65(b)(7), one commenter recommended changing the language to delete the age restriction in the language relating to dialysis technicians in performing treatments for pediatric patients. The commenter stated that size, not age should be the determining factor in providing dialysis treatment and that an individual weighing more than 20 kilograms is sufficient in size that technicians could safely provide the care.

Response: The department disagrees that size should be the only factor determining the care provided to a dialysis patient. Age impacts the physical and mental maturity of the patient; younger patients demonstrate greater and more frequent needs for psychosocial, dietary, medical, or nursing assessment. The age and size limits were not deleted but were amended.

Comment: Regarding §117.81, one commenter opposed the department's regulatory role mandated by the Health and Safety

Code, Chapter 251, expressing concern that the department's role would "undermine and subvert" the working relationship between the Network MRB and dialysis facilities. The commenter suggested that the MRB report to the department only level two or three corrective action plan recommendations. The commenter also expressed concern that the data reported to the department in the annual report would be used inappropriately by nondialysis personnel including the news media.

Response: The department understands and respects the commenter's concerns and agrees that the working relationship between the MRB and dialysis facilities should be preserved to continue its role as a supporting partner in improving the quality of dialysis care delivered. The department disagrees that the rules as written will undermine this relationship and is committed to develop a partnership with the MRB through the sharing of information the department is authorized to collect and which is not currently collected by the MRB. Further, the Health and Safety Code, §251.015(c) specifies that the information collected and recommendations made by the MRB to the department are confidential, may not be made available for public inspection, are not subject to disclosure under the Government Code, Chapter 552, or to discovery, subpoena or other compulsory legal process.

Comment: Regarding §117.81(b), one commenter objected to the department appointing a monitor to oversee or supervise a corrective action plan, stating that quality issues should be the purview of MRB.

Response: The department disagrees. The language relating to the use of a monitor to supervise the implementation of a corrective action plan is statutory language and, therefore was not changed.

Comment: Regarding §117.81(b), one commenter suggested that the department should be precluded from taking enforcement action if the department finds that a facility has implemented an acceptable plan of correction.

Response: The department disagrees. Such a preclusion would not allow for adequate enforcement of the rules and the statute. The department does not take lightly the imposition of administrative penalties, temporary manager, suspension, revocation or denial of a license. Such serious enforcement tools are used in situations where the department finds egregious violations relating to a patient's health and safety or when a facility demonstrates a history of noncompliance (e.g. the department's and/or MRB's efforts to work with a facility on compliance issues have failed). Therefore, the language was not changed.

Comment: Regarding §117.82(b), one commenter stated that the involuntary appointment of a temporary manager is a very serious matter, and requires the use of a temporary manager who is qualified by virtue of previous end stage renal disease facility management.

Response: The department agrees that involuntary appointment of a temporary manager is serious and does not consider taking such action frivolously. The department will work closely with the MRB in considering the appropriateness of appointing a temporary manager and to locate an individual qualified to perform this serious charge.

Comment: Regarding §117.81(b)(3), one commenter asked the department to provide more detail on the use of a corrective action plan resulting from an inspection.

Response: The department agrees to provide more detail and has done so by adding subparagraphs (A)-(F) to §117.81(b)(3), and §117.81(b)(4) to make clear that the department or a monitor may supervise or monitor the implementation of the corrective action plan.

Comment: Regarding §117.81(b)(6)(A) and (B), one commenter recommended that the department consider other options to the appointment of a temporary manager, including frequent communication with the facility, area or regional manager, or more frequent inspections.

Response: The department will not impose involuntary appointment of a temporary manager unless all other methods to obtain facility compliance are exhausted. If involuntary appointment of a temporary manager is imposed, the department with MRB participation would have already used the methods mentioned by the commenter prior to taking such action. The department has not changed the requirement except that the language in proposed §117.81(b)(6)(A) and (B) was condensed into §117.81(b)(6) and paragraphs (A) and (B) were deleted.

The department received approximately 480 letters which included an estimated 1,300 comments from patients, patient family members, registered nurses, licensed vocational nurses, social workers, dietitians, dialysis technicians, physicians, facility administrators and the following organizations or associations: End Stage Renal Disease Network of Texas, Inc. (Network #14) Medical Review Board, Texas Medical Association/ Renal Physicians of Texas Ad Hoc Work Group on ESRD Proposed Rules, American Nephrology Nurses Association, Texas Nurse's Association, National Medical Care, Inc., Council of Nephrology Social Workers of the National Kidney Foundation of Texas, National Association of Social Workers Texas Chapters, VIVRA Renal Care, Dallas Dietetic Association, University of Texas/Texas Department of Criminal Justice Managed Care Division, North Texas Council of Nephrology Social Workers, American Association of Kidney Patients, and department staff.

The commenters were generally for the adoption; however, they had questions, recommendations and concerns regarding specific provisions in the rules.

Subchapter A. General Provisions

25 TAC §§117.1–117.3

The new rules are adopted under the Health and Safety Code, §251.003 which provides the board with authority to adopt rules to implement the statute, including requirements regarding the issuance, renewal, denial, suspension, and revocation of an ESRD license; §251.014 regarding minimum standards for the protection of the health and safety of an ESRD facility patient, including the qualifications and supervision of the professional staff (including physicians) and other personnel, the equipment used by the facility, the sanitary and hygienic conditions in the facility, quality assurance for patient care, the provision and coordination of treatment and services by the facility, clinical records maintained by the facility, design and space requirements for safe access and ensuring patient privacy, indicators of quality of care, and water treatment and reuse

by the facility; and §251.032 regarding minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians, the determination of the competency of individuals who have been trained as dialysis technicians, and the acts and practices that are allowed or prohibited for dialysis technicians; and under Health and Safety Code, §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department and the commissioner of health.

§117.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

Advanced practice nurse-A registered nurse approved by the Board of Nurse Examiners for the State of Texas to practice as an advanced practice nurse on the basis of completion of an advanced educational program. The term includes a nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist.

Applicant-The owner of an end stage renal disease facility which is applying for a license under the statute.

Board-The Texas Board of Health.

Charge nurse-A person who has the qualifications described in §117.44(c)(2) and (3) of this title (relating to Qualifications of Staff).

Chief technician-The facility-based supervisor of the facility's mechanical, reuse and water treatment systems.

Commissioner-The commissioner of health.

Competency-The demonstrated ability to carry out specified tasks or activities with reasonable skill and safety that adheres to the prevailing standard of practice.

Core staff members-The facility's medical director, supervising nurse, dietitian, social worker, administrator, and chief technician.

Delegation-The transfer to a qualified and properly trained individual of the authority to perform a selected task or activity in a selected situation.

Department-The Texas Department of Health.

Dialysis-A process by which dissolved substances are removed from a patient's body by diffusion, osmosis and convection (ultrafiltration) from one fluid compartment to another across a semipermeable membrane.

Dialysis technician-An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician.

Dietitian-A person who is currently licensed under the laws of this state to use the title of licensed dietitian, is eligible to be a registered dietitian, and has one year of experience in clinical dietetics after becoming eligible to be a registered dietitian.

Director-The director of the Health Facility Licensing Division of the department or his or her designee.

End stage renal disease-That stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life.

End stage renal disease facility-A facility that provides dialysis treatment or dialysis training to individuals with end stage renal disease.

Full-time-The time period established by a facility as a full working week, as defined and specified in the facility's policies and procedures.

Full-time equivalent-Work time equivalent to 2,080 per 12 consecutive months.

Interdisciplinary team-A group composed of the patient and the primary physician, the registered nurse, the dietitian and the social worker who are responsible for planning care for the patient.

Intermediate level disinfection-A surface treatment using chemical germicides or disinfectants which are capable of inactivating various classes of microorganisms including, but not limited to, viruses (primarily medium to large viruses and lipid-containing viruses), fungi, and actively growing bacteria (including tubercle bacteria) when such chemical germicides or disinfectants are used in accordance with the manufacturer's instructions or per established guidelines. Intermediate level disinfection is generally not effective in inactivating or eliminating bacterial endospores. Examples of intermediate level disinfectants include bleach, 70-90% ethanol or isopropanol, and certain phenolic or iodophor preparations.

Inspection-An investigation or survey conducted by a representative of the department to determine if an applicant or licensee is in compliance with this chapter.

Licensed nurse-A registered nurse or licensed vocational nurse.

Licensed vocational nurse (LVN)-A person who is currently licensed under the laws of this state to use the title licensed vocational nurse and who may provide dialysis treatment after meeting the competency requirements specified for dialysis technicians.

Medical director-A physician who:

(A) is board eligible or board certified in nephrology or pediatric nephrology by a professional board; or

(B) during the five-year period prior to September 1, 1996, has served for at least 12 months as director of a dialysis program.

Medical review board-A medical review board that is appointed by a renal disease network organization which includes this state,with the network having a contract with the Health Care Financing Administration of the United States Department of Health and Human Services under 42 United States Code §1395rr.

Owner-One of the following which holds or will hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a limited liability company;

(C) an individual;

(D) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;

(E) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or

(F) all co-owners under any other business arrangement.

Patient care plan-A written document prepared by the interdisciplinary team for a patient receiving end stage renal disease services.

Pediatric patient-An individual 18 years of age or younger under the care of a facility.

Person-An individual, corporation, or other legal entity.

Physician-In individual who is licensed to practice medicine under the Medical Practice Act, Texas Civil Statutes, Article 4495b.

Physician assistant-A person who is licensed as a physician assistant under the Physician Assistant Licensing Act, Texas Civil Statutes, Article 4495b-1.

Presurvey conference-A conference held with department staff and the applicant or his or her representatives to review licensure standards and survey documents and provide consultation prior to the on-site licensure inspection. The applicant's representatives shall include an individual who will be responsible for the day-to-day supervision of care by the facility.

Product water-The effluent water from the last component of the facility's water treatment system.

Progress note-A dated and signed written notation by a facility staff member summarizing facts about care and a patient's response during a given period of time.

Registered nurse (RN)-A person who is currently licensed under the laws of this state as a registered nurse.

Social worker-A person who:

(A) is currently licensed as a social worker under the Human Resources Code, Chapter 50, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or

(B) has worked for at least two years as a social worker, one year of which was in a dialysis facility or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who has a masters degree from a graduate school of social work accredited by the Council on Social Work Education.

Supervising nurse (also may be known as the director of nursing)-An RN who:

(A) has at least 18 months experience as an RN, which includes at least 12 months experience in dialysis which has been obtained within the last 24 months; or

(B) has at least 18 months experience as an RN and holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis. Supervision-Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Immediate supervision means the supervisor is actually observing the task or activity as it is performed. Direct supervision means the supervisor is on the premises but not necessarily immediately physically present where the task or activity is being performed. Indirect supervision means the supervisor is not on the premises but is accessible by two-way communication and able to respond to an inquiry when made, and is readily available for consultation.

Statute-The Health and Safety Code, Chapter 251.

Training-The learning of tasks through on-the-job experience or instruction by an individual who has the capacity through education or experience to perform the task or activity to be delegated.

§117.3. Licensing Fees.

(a) The schedule of fees for licensure of a facility is as follows:

(1) initial license fee-$2,000;

(2) renewal license fee-$.25 per treatment, with a minimum renewal fee of $1,000 and a maximum renewal fee of $2,500; and

(3) change of ownership license fee-

(A) $1,000 if the inspections described in §117.11(h) of this title (relating to Application and Issuance of Temporary Initial License) and §117.12(a) of this title (relating to Issuance and Renewal of Annual License) are waived by the Texas Department of Health (department); or

(B) $2,000 if the department conducts the inspections described in §117.11(h) of this title (relating to Application and Issuance of Temporary Initial License) and §117.12(a) of this title (relating to Issuance and Renewal of Annual License).

(b) A facility owned or operated by a state agency is not required to pay a license fee.

(c) The department will not consider an application as officially submitted until the applicant pays the licensing fee. The fee must accompany the application form.

(d) A fee paid to the department is not refundable.

(e) Any remittance submitted to the department in payment of a required fee must be in the form of a certified check, money order, or personal check made out to the Texas Department of Health.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 16, 1996.

TRD-9612062
Susan K. Steeg
General Counsel
Texas Department of Health
Effective date: September 6, 1996
Proposal publication date: April 12, 1996
For further information, please call: (512) 458–7236

♦ ♦ ♦

Subchapter E. Application and Issuance of License

25 TAC §§117.11–117.16

The new rules are adopted under the Health and Safety Code, §251.003 which provides the board with authority to adopt rules to implement the statute, including requirements regarding the issuance, renewal, denial, suspension, and revocation of an ESRD license; §251.014 regarding minimum standards for the protection of the health and safety of an ESRD facility patient, including the qualifications and supervision of the professional

staff (including physicians) and other personnel, the equipment used by the facility, the sanitary and hygienic conditions in the facility, quality assurance for patient care, the provision and coordination of treatment and services by the facility, clinical records maintained by the facility, design and space requirements for safe access and ensuring patient privacy, indicators of quality of care, and water treatment and reuse by the facility; and §251.032 regarding minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians, the determination of the competency of individuals who have been trained as dialysis technicians, and the acts and practices that are allowed or prohibited for dialysis technicians; and under Health and Safety Code, §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department and the commissioner of health.

§117.11. Application and Issuance of Temporary Initial License.

(a) All first-time applications for a license are applications for a temporary initial license. The application for a temporary initial license is also an application for an annual license.

(b) Upon written request, the Texas Department of Health (department) shall furnish a person with an application form for a license.

(c) The applicant shall be at least 18 years of age if the applicant is an individual.

(d) The applicant shall retain a copy of all documentation that is submitted to the department.

(e) The applicant shall submit the following to the department:

(1) an accurate and complete application which contains original signatures;

(2) the initial license fee;

(3) the name of the owner of the facility;

(4) the name(s) and credentials of the medical director or at least one physician on staff at the facility who is qualified to serve as the medical director;

(5) for a facility providing end stage renal disease services prior to September 1, 1996, a notarized attestation that each dialysis technician on staff as of September 1, 1996, will have completed the training and competency evaluation programs described in §117.62 of this title (relating to Training Curricula and Instructors) and §117.63 of this title (relating to Competency Evaluation). A facility initiating end stage renal disease services on or after September 1, 1996, shall submit a notarized attestation that each dialysis technician on staff has completed the training competency evaluation programs;

(6) the organizational structure which includes the name(s) and business address(es) of each person who owns at least 5% interest in the applicant, a list of management and supervisory personnel, and a job description for each administrative and supervisory position;

(7) a written plan for the orderly transfer of care of the applicant's patients and clinical records if the applicant is unable to maintain services under the license;

(8) if an applicant is a corporation, a current letter from the state comptroller's office stating the corporation is in good standing or a notarized certification that the tax owed to the state under the Tax Code, Chapter 171, is not delinquent or that the corporation is exempt from the payment of the tax and is not subject to the Tax Code, Chapter 171; and

(9) a copy of an approved fire safety inspection report from the local fire authority in whose jurisdication the facility is based that is dated no earlier than 12 months prior to the date of application.

(f) Upon receipt of the application, including the required documentation and the fee, the department shall review the material to determine whether it is complete.

(1) All documents submitted with the original application shall be notarized copies or originals.

(2) The time periods for processing an application shall be in accordance with §117.14 of this title (relating to Time Periods for Processing and Issuing Licenses).

(g) Once the application is complete, a presurvey conference will be held at the office designated by the department. All applicants are required to attend a presurvey conference unless the designated survey office waives the requirement.

(h) The department shall conduct an inspection to determine compliance with the design and space requirements described in §117.31 of this title (relating to Design and Space Requirements) prior to issuance of the temporary initial license, unless the department waives the requirement.

(i) After completion of the presurvey conference and if the facility is in compliance with the design and space requirements, the department will issue a temporary initial license. The temporary initial license expires on the earlier of:

(1) the date the department issues or denies the annual license; or

(2) the date six months after the date the temporary initial license was issued.

(j) For the period beginning September 1, 1996, and ending August 31, 1997, the department may issue a second temporary initial license to an applicant in order to complete the inspections described in subsection (h) of this section and §117.12(a) of this title (relating to Issuance and Renewal of Annual License).

(k) Continuing compliance with this chapter is required during the temporary initial license period in order for an annual license to be issued.

(l) If the department determines that compliance with the requirements of this chapter is not substantiated after the issuance of the temporary initial license, the department may propose to deny the annual license and shall notify the applicant of a license denial as provided in §117.83 of this title (relating to Disciplinary Action).

(m) If an applicant decides not to continue the application process, the application may be withdrawn. If a license has been issued, the applicant shall return the license to the department with its written request to withdraw. The department shall acknowledge receipt of the request to withdraw. The license fee will not be refunded.

§117.15. Inspections.

(a) The Texas Department of Health (department) may conduct an inspection at any time to verify compliance with the statute and this chapter.

(b) After an inspection of a facility, the surveyor shall prepare and provide a statement of deficiencies, if any, to the person in charge of the facility. If deficiencies are identified after an inspection, the surveyor may request a corrective action plan. The facility shall prepare a corrective action plan in accordance with §117.81 of this title (relating to Corrective Action Plan).

(c) After review of a facility's annual report, the department may request additional information or conduct an inspection to determine compliance with the statute and this chapter.

(d) After a corrective action plan is accepted, the facility shall come into compliance 30 calendar days prior to the expiration date of the license or no later than the dates designated in the plan of correction, whichever comes first. A plan of correction date shall not exceed 45 days from the date the deficiency is cited.

(e) The department shall verify the correction of deficiencies by mail or an on-site inspection.

(f) Acceptance of a corrective action plan does not preclude the department from taking enforcement action as appropriate under Subchapter F of this chapter (relating to Enforcement).

(g) The following provisions address the transition for implementation of the statute and apply only to a facility providing services as of September 1, 1996.

(1) Prior to December 1, 1996, a facility shall make a good faith effort to comply with the following provisions:

(A) §117.43(e)(5)-(7) of this title (relating to Provision and Coordination of Treatment and Services) concerning nursing services;

(B) §117.43(g) of this title concerning dialysis technicians;

(C) §117.43(h)(5) of this title concerning nutrition services; and

(D) Subchapter E of this chapter (relating to Dialysis Technicians) concerning dialysis technician training curricula and instructors; competency evaluation; documentation of competency; and prohibited acts.

(2) A facility shall comply with all other applicable provisions of this chapter.

(3) The department shall not take enforcement action for a deficiency based on the provisions listed in paragraph (1) of this subsection unless the deficiency continues after December 1, 1996.

(4) A facility for which a deficiency was cited under the provisions listed in paragraph (1) of this subsection prior to December 1, 1996, shall file documentation with the department to show compliance with the cited provision listed in paragraph (1) of this subsection. The documentation shall be filed by January 1, 1997. The department may verify compliance through an on-site inspection.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 16, 1996.

TRD-9612063
Susan K. Steeg
General Counsel
Texas Department of Health
Effective date: September 6, 1996
Proposal publication date: April 12, 1996
For further information, please call: (512) 458–7236

♦ ♦ ♦

Subchapter C. Minimum Standards for Design and Space, Equipment, Water Treatment and Reuse, and Sanitary and Hygienic Conditions

25 TAC §§117.31–117.34

The new rules are adopted under the Health and Safety Code, §251.003 which provides the board with authority to adopt rules to implement the statute, including requirements regarding the issuance, renewal, denial, suspension, and revocation of an ESRD license; §251.014 regarding minimum standards for the protection of the health and safety of an ESRD facility patient, including the qualifications and supervision of the professional staff (including physicians) and other personnel, the equipment used by the facility, the sanitary and hygienic conditions in the facility, quality assurance for patient care, the provision and coordination of treatment and services by the facility, clinical records maintained by the facility, design and space requirements for safe access and ensuring patient privacy, indicators of quality of care, and water treatment and reuse by the facility; and §251.032 regarding minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians, the determination of the competency of individuals who have been trained as dialysis technicians, and the acts and practices that are allowed or prohibited for dialysis technicians; and under Health and Safety Code, §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department and the commissioner of health.

§117.31. Design and Space Requirements.

(a) General.

(1) The standards in this section shall apply only to a facility which initiates the provision of end stage renal disease services on or after September 1, 1996; or to the area of a facility affected by design and space modifications or renovations completed after September 1, 1996.

(2) A facility must provide a physical environment that protects the health and safety of patients, personnel and the public. The physical premises of the facility and those areas of the facility's surrounding physical structure that are used by the patients (including all stairwells, corridors and passageways) must meet the local building and fire safety codes as they relate to design and space requirements for safe access and patient privacy.

(3) A facility shall comply with Chapter 26 of the National Fire Protection Association 101, Code for Safety to Life from Fire in Buildings and Structures, 1994 Edition (NFPA 101), relating to new business occupancies, published by the National Fire Protection Association. All documents published by the NFPA as

referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, Batterymarch Park, Quincy, Massachussetts 02169, 1-800-344-3555.

(4) A facility shall provide a reception and information counter or desk and a waiting room separate from the patient treatment area. The waiting room shall provide adequate seating.

(5) The patient treatment area shall be designed and equipped to provide proper and safe treatment as well as privacy and comfort for patients. At a minimum, patient treatment stations shall be 70 square feet, with the smallest dimension at seven feet. The 70 square feet may include aisles or counters.

(6) If hepatitis B positive patients are treated, a separate room with its own designated machine(s), clamp(s), blood presure cuff(s), sink(s) and other equipment shall be used.

(7) A facility shall provide a call system in patient areas outside the treatment area (e.g., patient restrooms, training rooms, and examination rooms) which is usable by a collapsed patient lying on the floor (e.g., inclusion of a pull cord). Calls shall register at and activate a visible signal in the central nurses station. Call systems which provide two-way communication shall be equipped with an indicating light at each call station which lights and remains lighted as long as the voice circuit is operating.

(8) A facility shall have separate toilet and lavatory facilities for staff and patients.

(9) A facility shall provide a private area for meetings with patients or family members.

(10) A facility shall have a room for medical examinations which includes an examination table, a work counter, and a hand washing sink or lavatory.

(11) Telephone access shall be available in the facility to patients and family members.

(12) A facility located above the ground floor must have an elevator of sufficient size to accommodate a gurney available at all times.

(13) A facility shall provide two exits remote from each other in accordance with NFPA 101, §5-5.1.3. At least one exit door shall be accessible by an ambulance from the outside. This door may also serve as an entry for loading or receiving goods.

(14) A facility shall provide a separate room for peritoneal dialysis patients if the facility provides on-site peritoneal dialysis training. This room shall include a lavatory or sink for hand washing.

(15) Doors to an isolation room or peritoneal dialysis room shall not be lockable from inside the room.

(16) Public corridor widths and all other areas where patients may traverse shall accommodate wheel chair or gurney passage.

(17) Items such as drinking fountains, telephone booths, vending machines and portable equipment (including patient care equipment) shall be located so that they do not project into, restrict, or obstruct exit corridor traffic.

(18) A facility shall utilize a ventilation system which provides adequate comfort to patients during treatment and which minimizes the potential of insect access.

(19) Floors that are subject to traffic while wet shall have nonslip surfaces.

(b) Storage areas.

(1) All storage areas shall be kept clean and orderly at all times.

(2) A facility premises shall be kept free from accumulations of combustible materials not necessary for immediate operation of the facility. Local supplies of combustible liquids shall be stored in cabinets or shelves which are well-ventilated from top to bottom.

(3) A facility shall have a separate space for wheel chair storage.

(4) A facility shall store oxygen in compliance with §4-3 of the National Fire Protection Association 99, Standard for Health Care Facilities, 1993 Edition (NFPA 99) published by the National Fire Protection Association.

(c) Provisions for the handicapped.

(1) If Texas Civil Statutes, Article 9102 applies, a facility shall be designed in accordance with 16 Texas Administrative Code, Chapter 68 (relating to Elimination of Architectural Barriers) administered by the Texas Department of Licensing and Regulation, effective April 1, 1994.

(2) A facility shall meet applicable requirements of 29 United States Code, §794. When federal funds are used for construction, for program requirements, or for client services, the handicapped requirements of §794 will apply.

(3) A facility shall comply with the design and space requirements of the Americans with Disabilities Act, 42 United States Code, §12182(b)(2)(A)(iv) and (v) and §12183, and the regulations and guidelines promulgated under §12186(b) and (c) and §12204, effective July 28, 1991.

(d) Fire protection.

(1) All sprinkler systems, smoke detectors, and other fire-fighting equipment shall be inspected and tested at least once each year to maintain it in serviceable condition. If a facility has a sprinkler system, the sprinkler system shall be installed and maintained in accordance with the National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 1994 Edition, published by the National Fire Protection Association.

(2) A facility shall have an emergency lighting system capable of providing sufficient illumination to allow safe evacuation from the building. Battery pack systems shall be maintained and tested quarterly. If a facility maintains a back-up generator, the generator must be installed, tested and maintained in accordance with the National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 1993 Edition (NFPA 110), published by the National Fire Protection Association.

(3) A facility housed in or adjacent to a building classified as a "high hazard industrial occupancy," as defined in §28-1.4.1 of the NFPA 101, must have a special feature such as a two-hour fire wall between the facility and the other occupancy and written approval by the fire authority having jurisdiction.

(e) Construction. If construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of patients during the construction.

(f) Other standards. A facility may impose more stringent design and space standards than the minimum standards in this section.

§117.32. Equipment.

(a) All equipment used by a facility, including backup equipment, shall be maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(1) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.

(2) Medical equipment that malfunctions must be immediately removed from service until the malfunction is identified and corrected.

(3) Written evidence of all maintenance and repairs shall be maintained.

(4) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service.

(5) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), relating to reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(b) A facility shall develop, implement and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility or provided by a facility for use by the patient in the patient's home receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.

(c) At least one complete dialysis machine shall be available on-site as backup for every ten dialysis machines in use.

(d) If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population

(e) All equipment and appliances shall be properly grounded in accordance with the National Fire Protection Association 99, Standard for Health Care Facilities, §§3-4.1 and 7-5.1, 1990 Edition (NFPA 99), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, Batterymarch Park, Quincy, Massachussetts 02169, 1-800-344-3555.

(f) Extension cords and cables shall not be used for permanent wiring.

(g) A facility shall have emergency equipment and supplies immediately accessible in the treatment area.

(1) At a minimum, the emergency equipment and supplies shall include the following:

(A) oxygen;

(B) ventilatory assistance equipment, to include airways, manual breathing bag, and mask;

(C) suction equipment;

(D) supplies specified by the medical director; and

(E) electrocardiograph.

(2) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in paragraph (1) of this subsection for this special population.

(3) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.

(h) If a facility employs a central delivery system for glucose-containing bicarbonate dialysate, the system must be drained at the end of each treatment day and cultured weekly to identify potential bacterial contamination. If cultures demonstrate more than 2,000 colony forming units (CFUs) per milliliter, the bicarbonate delivery system must be disinfected and recultured.

§117.33. Water Treatment and Reuse.

(a) Compliance required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements for water treatment and reuse of hemodialyzers than the minimum standards required by this section.

(b) Water treatment.

(1) The design for the water treatment system in a facility shall be based on considerations of the source water for the facility and designed by a water quality professional with education, training, or experience in dialysis system design.

(2) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system as described in 30 Texas Administrative Code, §290.104 (relating to Control Tests), §290.105 (relating to Maximum Contaminant Levels (MCLs) for Microbiological Contaminants), and §290.106 (relating to Bacteriological Monitoring) as adopted by the Texas Natural Resources Conservation Commission, effective January 1991.

(3) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.

(4) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §3.2.1 (relating to Hemodialysis Systems) and §3.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 3330 Washington Boulevard, Suite 400, Arlington, Virginia 22201.

(5) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed in writing and known to the operator. The facility shall establish and post in the water area written procedures describing the action to be taken when parameters are not met.

(6) Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series. If the source water is from a private supply which does not use chlorine/chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

(A) Reverse osmosis membranes, if used, shall meet the standards in §3.2.3.5 (relating to Reverse Osmosis) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the AAMI.

(B) Deionization systems, if used, shall meet the standards in §§3.2.3.3 (relating to Regenerated or Reconstituted Devices) and 3.2.3.4 (relating to Deionization) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the AAMI.

(C) The carbon tanks must contain acid washed 30-mesh or smaller carbon placed in series with a minimum empty bed contact time of three minutes for each tank or bank of tanks and a testing port between the tanks or bank of tanks. Water from this port(s) must be tested for chlorine/chloramine levels prior to each patient shift. The first test each treatment day for chlorine/chloramine shall be done no sooner than 15 minutes after start-up of the water treatment system.

(D) Test results of greater than 0.5 parts per million (p.p.m.) for chlorine or 0.1 p.p.m. for chloramine from the port between the initial tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s). If test results at the exit of the final tank(s) are greater than the parameters for chlorine or chloramine described in this subparagraph, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine/chloramine and the medical director shall be notified.

(7) Water softeners, if used, shall have the capacity to treat a sufficient volume of water to supply the facility for the entire treatment day.

(8) Cartridge filters, if used, shall be made of material (e.g., pure polypropylene) which will not leach surfactants, formaldehyde, or other material which has been used in their manufacture.

(9) Cartridge filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

(10) The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specified parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components shall be located after the sensing cell.

(11) When deionization tanks do not follow a reverse osmosis system, parameters for the rejection rate of the membranes must assure that the lowest rate accepted would provide product water in compliance with §3.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Hemodialysis Systems, March 1992 Edition published by the AAMI.

(12) A facility shall maintain written logs of the operation of the water treatment system for each treatment day. The log book shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

(13) Microbiological testing of product water shall be conducted monthly and following any repair or change to the water treatment system. The results must demonstrate that water quality meets §3.2.1 (relating to Hemodialysis Systems) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the AAMI. Sample sites chosen for the testing shall include the beginning of the distribution piping, the product water in the reuse room, and the end of the distribution piping. If the results do not meet the AAMI standard described in this paragraph, the water system shall be immediately disinfected and recultured. If after disinfection, the cultures do not meet the AAMI standards described in this paragraph, the facility shall determine the source of contamination by immediately reculturing the sample sites, all patient stations, any water storage tanks, water used to mix dialysate, and product water from the final component of the water treatment system.

(14) A sample of product water must be submitted for chemical analysis every six months and must demonstrate that water quality meets §3.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the AAMI. The sample water for chemical analysis shall be drawn after the quality monitoring sensing cell. Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of a reverse osmosis system decreases 5.0% or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

(15) Facility records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

(16) Only persons qualified by the education or experience described in §117.44(f) of this title (relating to Qualifications of Staff) may repair or replace components of the water treatment system. Documentation of education or training which qualifies these persons must be maintained on file in the facility.

(c) Reuse of hemodialyzers and related devices.

(1) Reuse practice in a facility must comply with the American National Standard, Reuse of Hemodialyzers, 1993 Edition published by the AAMI.

(2) A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only.

(3) Arterial lines may be reused only when the arterial lines are labeled to allow for reuse by the manufacturer and the manufacturer-established protocols for the specific line have been approved by the United States Food and Drug Administration.

(4) The water supply in the reuse room shall incorporate a check valve to prevent chemical agents used from inadvertently back flowing into the water distribution system.

(5) Ventilation systems in the reuse room shall be connected to an exhaust system to the outside which is separate from the building exhaust system, have an exhaust fan located at the discharge end of the system, and have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the system. Exhaust outlets shall be above the roof level and arranged to minimize recirculation of exhaust air into the building.

(6) A facility shall establish, implement, and enforce a policy for dialyzer reuse criteria (including any facility-set number of reuses allowed) which is included in patient education materials and posted in the waiting room and patient treatment areas.

(7) A facility shall consider and address the health and safety of patients sensitive to disinfectant solution residuals.

(8) A facility shall provide each patient with information regarding the reuse practices at the facility, the opportunity to tour the reuse area, and the opportunity to have questions answered.

(9) A facility shall restrict the reprocessing room to authorized personnel.

(10) A facility shall obtain written informed consent of the patient or legal representative.

(d) Centralized dialyzer reprocessing. If a facility participates in centralized reprocessing in which dialyzers from multiple facilities are reprocessed at one site, the facility shall:

(1) require the use of automated reprocessing equipment;

(2) maintain responsibility and accountability for the entire reuse process;

(3) adopt, implement, and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the off-site location does not increase contamination of the dialyzers, staff, or the environment; and

(4) provide department staff access to the off-site reprocessing site as part of a facility inspection.

§117.34. Sanitary Conditions and Hygienic Practices.

(a) General infection control measures.

(1) Universal precautions.

(A) Universal precautions shall be followed in the facility for all patient care activities in accordance with 29 Code of Federal Regulations, §1910.1030 (d)(1)-(3) (relating to Bloodborne Pathogens) and the Health and Safety Code, Chapter 85, Subchapter I (relating to Prevention of HIV and Hepatitis B Virus by Health Care Workers).

(B) Facility staff shall wash their hands before and after each patient contact in which there is a potential exposure to blood or body fluids. Location and arrangement of hand washing facilities shall permit ease of access and proper use.

(i) Hand washing sinks shall be readily accessible in each patient care area.

(ii) All fixtures and lavatories shall be trimmed with valves which can be operated without the use of hands. There shall be sufficient clearance for the operation of blade-type handles, if they are used.

(iii) Provisions for hand drying shall be included at all hand washing facilities.

(C) Facility staff shall explain the potential risks associated with blood and blood products to patients and family members and provide the indicated personal protective equipment to a patient or family member if the patient or family member assists in procedures which could result in contact with blood or body fluids.

(2) Documentation and coordination of infection control activities.

(A) The facility must designate a person to monitor and coordinate infection control activities.

(B) A facility shall develop and maintain a system to identify and track infections to allow identification of trends or patterns. This activity shall be reviewed as a part of the facility's quality assurance program described in §117.41 of this title (relating to Quality Assurance for Patient Care). The record shall include trends, corrective actions, and improvement actions taken.

(3) Smoking policy. The facility shall establish, implement, and enforce a smoking policy.

(b) Environmental infection control.

(1) General procedures.

(A) A facility shall provide and actively monitor a sanitary environment which minimizes or prevents transmission of infectious diseases.

(i) The facility shall provide a janitor's closet with space for cleaning supplies and equipment.

(ii) Wall bases in patient treatment and other areas which are frequently subject to wet cleaning methods shall be tightly sealed to the floor and the wall, impervious to water and constructed without voids that can harbor insects.

(iii) Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. In all areas subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions.

(iv) Wall finishes shall be washable and, in the immediate areas of plumbing fixtures, smooth and moisture resistant.

(v) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(vi) All exposed ceilings and ceiling structures in areas normally occupied by patients, staff, and visitors shall be finished so as to be cleanable with equipment used in daily housekeeping activities. Ceiling tiles stained with blood shall be cleaned or replaced.

(vii) Ceiling fans shall not be utilized in patient treatment areas.

(B) Blood spills shall be cleaned immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.

(i) The surface should be subjected to intermediate level disinfection in accordance with the manufacturer's instructions, if a commercial liquid chemical disinfectant is used.

(ii) If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and the surface to be treated must be compatible with this type of chemical treatment.

(2) Specific procedures for equipment and dialysis machines.

(A) Routine disinfection of active and backup dialysis machines shall be performed according to facility defined protocol, accomplishing at least intermediate level disinfection.

(B) Samples of dialysate from machines chosen at random shall be cultured monthly, and culture results shall not exceed 2,000 colony forming units per milliliter. Hemodialysis machines of home patients shall be cultured monthly until results not exceeding 2,000 colony forming units per milliliter are obtained for three consecutive months, then quarterly samples shall be cultured.

(C) Between patient shifts, facility staff shall clean machine exteriors, treatment chairs, tourniquets, and hemostats. Blood pressure cuffs which become contaminated with blood shall be removed from service, disinfected, and allowed to dry prior to being returned to use.

(c) Medical waste and liquid/sewage waste management.

(1) The facility shall comply with the requirements set forth by the department in §§1.131-1.137 of this title (relating to Definition, Treatment and Disposition of Special Waste from Health Care Related Facilities) and the Texas Natural Resource Conservation Commission's requirements in Title 30, Texas Administrative Code, §330.1004 (relating to Generators of Medical Waste).

(2) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the Texas Natural Resource and Conservation Commission in accordance with Title 30, Texas Administrative Code, Chapter 285 (relating to On-site Wastewater Treatment).

(d) Hepatitis B prevention.

(1) Prevention requirements concerning staff.

(A) Hepatitis B vaccination.

(i) The facility shall offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 Code of Federal Regulations, §1910.1030(f)(1)-(2) (relating to Bloodborne Pathogens).

(ii) Staff vaccination records shall be maintained in each staff member's health record.

(B) Serologic screening of staff.

(i) New staff members shall be screened for hepatitis B surface antigen (HBsAg) and the results reviewed prior to the staff providing patient care, unless the new staff member provides the facility documentation of positive serologic response to hepatitis B vaccine.

(ii) The facility shall establish, implement and enforce a policy for repeated serologic screening of staff. The repeated serologic screening shall be based on each staff member's HBsAg/antibody to HBsAg (anti-HBs), and shall be congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the United States Department of Health and Human Services (USDHHS). This document when referenced in this section may be obtained by writing or calling the USDHHS at the following address and telephone number: Public Health Service, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Hospital Infection Program, Mail Stop C01, Atlanta, Georgia 30333, 404-639-2318.

(2) Prevention requirements concerning patients.

(A) Hepatitis B vaccination.

(i) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Serologic screening of patients.

(i) Candidates for dialysis shall be screened for HBsAg within one month before or at the time of admission to the facility.

(ii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(I) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the United States Department of Health and Human Services.

(C) Isolation procedures for the HBsAg-positive patient.

(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a handwashing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(iii) If an HBsAg-positive patient is discharged, the equipment which had been reserved for that patient shall be given intermediate level disinfection prior to use for a patient testing negative for HBsAg.

(iv) A patient who is admitted for treatment before results of HBsAg testing are known shall undergo treatment as if the HBsAg test results were potentially positive, except that such a patient shall not be treated in the HBsAg isolation room, area, or machine.

(I) If a central delivery system is used by the facility, the facility shall treat potentially HBsAg-positive patients on the last machine on the loop and may not reuse the dialyzer until the HBsAg test results are known.

(II) The dialysis machine used by this patient shall be given intermediate level disinfection prior to its use by another patient.

(III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(e) Tuberculosis prevention.

(1) Prevention requirements concerning staff.

(A) Facility staff shall be screened for tuberculosis upon employment or receiving privileges as a member of the medical staff and prior to patient contact.

(B) Subsequent screening of facility staff shall be performed after any potential exposure to laryngeal or pulmonary tuberculosis.

(C) Respiratory isolation procedures and precautions developed by the facility shall be employed by facility staff providing treatment to patients with pulmonary tuberculosis.

(2) Prevention requirements concerning patients.

(A) If the facility treats active pulmonary tuberculosis patients, a separate room with an isolated air handling system shall be utilized for these patients.

(B) The facility shall screen patients for tuberculosis when indicated by the presence of risk factors for, or the signs and symptoms of tuberculosis. Screening shall be performed after potential exposure to active laryngeal or pulmonary tuberculosis.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 16, 1996.

TRD-9612068
Susan K. Steeg
General Counsel
Texas Department of Health
Effective date: September 6, 1996
Proposal publication date: April 12, 1996
For further information, please call: (512) 458–7236

♦ ♦ ♦

Subchapter D. Minimum Standards for Patient Care and Treatment

25 TAC §§117.41–117.45

The new rules are adopted under the Health and Safety Code, §251.003 which provides the board with authority to adopt rules to implement the statute, including requirements regarding the issuance, renewal, denial, suspension, and revocation of an ESRD license; §251.014 regarding minimum standards for the protection of the health and safety of an ESRD facility patient, including the qualifications and supervision of the professional staff (including physicians) and other personnel, the equipment used by the facility, the sanitary and hygienic conditions in the facility, quality assurance for patient care, the provision and coordination of treatment and services by the facility, clinical records maintained by the facility, design and space requirements for safe access and ensuring patient privacy, indicators of quality of care, and water treatment and reuse by the facility; and §251.032 regarding minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians, the determination of the competency of individuals who have been trained as dialysis technicians, and the acts and practices that are allowed or prohibited for dialysis technicians; and under Health and Safety Code, §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department and the commissioner of health.

§117.41. Quality Assurance for Patient Care.

(a) A facility shall perform a systematic, ongoing, concurrent and comprehensive review of the care provided. The review shall be specific to the facility. A facility shall adopt, implement, and enforce a quality assurance program based on the May 8, 1996 edition of the Criteria and Standards, Dialysis Facility Specific Quality Management Program, §J, Pages 1-2 as published by the End Stage Renal Disease Network of Texas, Inc., 1755 North Collins Boulevard, Suite 221, Richardson, Texas 75080, 214-669-3311.

(b) Quality management activities shall demonstrate that facility staff evaluate the provision of dialysis care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until resolution is achieved. Evidence shall support that aggregate patient data including identification and tracking of patient infections, is continuously reviewed for trends.

(c) Core staff members shall actively participate in the quality management activities.

(d) A facility shall conduct quality management meetings monthly or more often as necessary to identify or correct problems. The meetings shall be documented in written minutes which are maintained in the facility.

(e) A record of each accident or incident occurring in a facility, including medication errors and adverse drug reactions, shall be prepared immediately.

(f) The facility shall report the following to the director within three working days of the occurrence:

(1) an accident or incident resulting in death or hospitalization of a patient;

(2) conversion of staff or a patient to HBsAg positive; or

(3) fire.

§117.43. Provision and Coordination of Treatment and Services.

(a) Patient rights. Each facility shall adopt, implement, and enforce policies and procedures appropriate to the patient population served which ensure that each patient is:

(1) treated with respect, dignity, and full recognition of the patient's individuality and personal needs;

(2) provided privacy and confidentiality, for the patient and the clinical record;

(3) provided a safe and comfortable treatment environment;

(4) provided information in a manner to facilitate understanding by the patient and the patient's legal representative, family or significant other. Written patient information materials shall be available, with materials in languages other than English if the census of the facility includes more than four patients who read that primary language. In lieu of written materials in the patient's primary language, an interpreter may be provided if documentation and patient interview support that information sufficient to allow the patient to participate in the treatment has been communicated;

(5) informed by a physician of the patient's medical status;

(6) informed of all treatment modalities and settings for the treatment of end stage renal disease;

(7) informed about and participates in, if desired, all aspects of care, including the right to refuse treatment, and informed of the medical consequences of such refusal;

(8) aware of all services available in the facility and the charges for services provided;

(9) informed about the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are used to describe a facility and its services, the brochures shall contain a statement with respect to reuse;

(10) assured of a reasonable response by the facility to the patient's requests and needs for treatment or service, within the facility's capacity, the facility's stated mission, and applicable law and regulation;

(11) provided hours of dialysis that are scheduled for patient convenience whenever feasible or possible. Consideration shall be given to a patient's work or school schedule;

(12) transferred only for medical reasons, for the patient's welfare or that of other patients or staff members, or for nonpayment of fees. A patient shall be given advance notice to ensure orderly transfer or discharge;

(13) provided information regarding advance directives and allowed to formulate such directives to the extent permitted by law. This includes documents executed under the Natural Death Act, Health and Safety Code, Chapter 672; Civil Practice and Remedies Code, Chapter 135 relating to durable power of attorney for health care; and Health and Safety Code, Chapter 674 relating to out-of-hospital do-not-resuscitate;

(14) aware of the mechanisms and agencies to express a complaint against the facility without fear of reprisal or denial of services. A facility shall provide to each individual who is admitted to the facility a written statement that informs the individual that a complaint against the facility may be directed to the department. The statement shall be provided at the time of admission and shall advise the patient that registration of complaints may be filed with the director, Health Facility Licensing Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199, 1-800-228-1570; and

(15) fully informed of the rights listed in this subsection, the responsibilities established by the facility, and all rules and regulations governing patient conduct and responsibilities. A written copy of the patient's rights and responsibilities shall be provided to each patient or the patient's legal representative upon admission and a copy shall be posted with the facility license.

(b) Patient care plan.

(1) A facility shall establish, implement, and enforce a policy whereby patient services are coordinated using an interdisciplinary team approach. The interdisciplinary team shall consist of the patient's primary dialysis physician, registered nurse, social worker, and dietitian.

(2) The interdisciplinary team shall develop a written, individualized, comprehensive patient care plan that specifies the services necessary to address the patient's medical, psychological, social, and functional needs, and includes treatment goals.

(3) The patient care plan shall include evidence of coordination with other service providers (e.g. hospitals, long term care facilities, home and community support services agencies, or transportation providers) as needed to assure the provision of safe care.

(4) The patient care plan shall include evidence of the patient's (or patient's legal representative's) input and participation, unless they refuse to participate. At a minimum, the patient care plan shall demonstrate that the content was shared with the patient or the patient's legal representative.

(5) The patient care plan shall be developed within 30 days from the patient's admission to the facility and updated as indicated by any change in the patient's medical, nutritional, or psychosocial condition, or at least every six months. Evidence of the review of the patient care plan with the patient and the interdisciplinary team to evaluate the patient's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, shall be documented and included in the patient's clinical record.

(c) Emergency preparedness.

(1) A facility shall implement written procedures which describe staff and patient actions to manage potential medical and non-medical emergencies, including but not limited to, fire, equipment failure, power outages, medical emergencies, and natural disasters which are likely to threaten the health or safety of facility patients, the staff, or the public.

(2) A facility shall have a functional plan to access the community emergency medical services.

(3) A facility shall have personnel qualified to operate emergency equipment and to provide emergency care to patients on-site and available during all treatment times. A charge nurse qualified to provide basic cardiopulmonary life support (BCLS) shall be on site and available to the treatment area whenever patients are present. All clinical staff members shall maintain current certification and competency in BCLS.

(4) A facility shall have a transfer agreement with one or more hospitals which provide acute dialysis service for the provision of inpatient care and other hospital services to the facility's patients. The facility shall have documentation from the hospital to the effect that patients from the facility will be accepted and treated in emergencies. There shall be reasonable assurances that:

(A) the transfer or referral of patients will be effected between the hospital and the facility whenever such transfer or referral

is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(B) the interchange of medical and other information necessary or useful in the care and treatment of the patient transferred will occur within one working day; and

(C) security and accountability will be assured for the transferred patient's personal effects.

(5) A facility shall establish, implement and enforce a written plan for the protection of patients in the event of a fire.

(A) An evacuation plan shall be developed and diagrams posted in conspicuous places.

(B) The facility shall provide approved fire extinguishing equipment adequate for the conditions involved. Every portable fire extinguisher maintained in the facility shall be installed and maintained in accordance with National Fire Protection Association 10, Standard for Portable Fire Extinguishers, 1994 Edition, and the National Fire Protection Association 101, Code for Safety to Life from Fire in Buildings and Structures, 1994 Edition, §26-3.5, published by the National Fire Protection Association, Post Office Box 9101, Batterymarch Park, Quincy, Massachussetts 02169, 1-800-344-3555. Fire extinguishers shall be refilled when necessary, kept in condition for instant use, and tagged or labeled to indicate the name, address, and telephone number of the person recharging the unit and the date of the last inspection. The hose, nozzle, gaskets, and all other parts shall be maintained in good repair at all times.

(C) The facility shall conduct fire drills at least every six months for each patient shift to include the use of alarms and equipment, and discussion with patients, visitors, employees and staff about the evacuation plan. Written reports shall be maintained to include evidence of staff and patient participation.

(D) All staff shall be familiar with the locations of fire-fighting equipment. Fire-fighting equipment shall be located so that a person shall not have to travel more than 75 feet from any point to reach the equipment.

(6) A written disaster preparedness plan specific to each facility shall be developed and in place. The plan shall be based on an assessment of the probability and type of disaster in each region and the local resources available to the facility. The plan shall include procedures designed to minimize harm to patients and staff along with ensuring safe facility operations. The plan and in-service programs for patients and staff shall include provisions or procedures for responsibility of direction and control, communications, alerting and warning systems, evacuation, and closure.

(d) Medication storage and administration.

(1) Pharmaceutical services shall be provided in accordance with accepted professional principles and federal and state laws and regulations.

(2) Medications shall be administered only if such medication is ordered by the patient's physician.

(3) All verbal or telephone orders shall be received by a licensed nurse or physician assistant and countersigned by the physician within 15 days.

(4) Medications maintained in the facility shall be properly stored and safeguarded in enclosures of sufficient size which are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain appropriate temperatures for such storage.

(5) A facility shall maintain an emergency stock of medications, as specified by the medical director, to treat the emergency needs of patients.

(6) Medications shall be prepared for administration in an area which includes a work counter and a sink. This area shall be located in such a manner as to prevent contamination of medicines being prepared for administration.

(7) Medications not given immediately shall be labeled with the patient's name, the name of the medication, the dosage prepared, and the initials of the person preparing the medication. All medications shall be administered by the individual who prepares them.

(8) All medications shall be administered by licensed nurses, physician assistants, or physicians except that intravenous normal saline, intravenous heparin, and subcutaneous lidocaine may be administered as part of a routine hemodialysis treatment by dialysis technicians qualified according to §117.62(b) and (f) of this title (relating to Training Curricula and Instructors) and §117.63(b), (c) and (e) of this title (relating to Competency Evaluation). Such administration by dialysis technicians shall be in compliance with the Medical Practice Act, Texas Civil Statutes, Article 4495b, §3.06(d), relating to the delegation of medical acts by a licensed physician in the State of Texas.

(e) Nursing services.

(1) Nursing services to prevent or reduce complications and to maximize the patient's functional status shall be provided to a patient and the patient's family or significant other.

(2) A full-time supervising nurse shall be employed to manage the provision of patient care.

(3) A registered nurse shall be responsible for:

(A) conducting admission nursing assessments;

(B) conducting assessments of a patient when indicated by a question relating to a change in the patient's status or at the patient's request;

(C) participating in team review of a patient's progress;

(D) recommending changes in treatment based on the patient's current needs;

(E) facilitating communication between the patient, patient's family or significant other, and other team members to ensure needed care is delivered;

(F) providing oversight and direction to dialysis technicians and licensed vocational nurses; and

(G) participating in continuous quality improvement activities.

(4) A charge nurse shall be on site and available to the treatment area to provide patient care during all dialysis treatments.

(5) At least one licensed nurse shall be available on-site to provide patient care for every ten patients or portion thereof.

This may include the charge nurse required by paragraph (4) of this subsection.

(6) If pediatric dialysis is provided, a registered nurse with experience or training in pediatric dialysis shall be available to provide care for pediatric dialysis patients younger than 14 years of age or smaller than 35 kilograms in weight.

(7) Sufficient direct care staff shall be on-site to meet the needs of the patients. The staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift. For pediatric dialysis patients, one licensed nurse shall be provided on-site for each patient weighing less than ten kilograms and one licensed nurse provided on-site for every two patients weighing from ten to 20 kilograms.

(8) A facility shall provide a nursing station(s) to allow adequate visual monitoring of patients by nursing staff during treatment.

(9) A licensed nurse or dialysis technician shall evaluate each patient before and after treatment according to facility policy and the staff member's level of training. A registered nurse shall conduct a patient assessment when indicated by a question relating to a change in the patient's status or at the patient's request.

(10) The initial nursing assessment shall be initiated by a charge nurse at the time of the first treatment in the facility and completed by a registered nurse within the first three treatments.

(f) Licensed vocational nurses. This chapter does not preclude a licensed vocational nurse (LVN) from practicing in accordance with the rules adopted by the Texas Board of Vocational Nurse Examiners. If the LVN is acting in the capacity of a dialysis technician, the facility shall determine that the LVN has passed a training and competency evaluation curriculum which meets the requirements in §117.62 of this title (relating to Training Curricula) and §117.63 of this title (relating to Competency Evaluation).

(g) Dialysis technicians. A dialysis technician providing direct patient care shall demonstrate knowledge and competency for the responsibilities specified in §117.62 of this title and §117.63 of this title.

(h) Nutrition services.

(1) Nutrition services shall be provided to a patient and the patient's caregiver(s) in order to maximize the patient's nutritional status.

(2) The dietitian shall be responsible for:

(A) conducting a nutrition assessment of a patient;

(B) participating in a team review of a patient's progress;

(C) recommending therapeutic diets in consideration of cultural preferences and changes in treatment based on the patient's nutritional needs in consultation with the patient's physician;

(D) counseling a patient, a patient's family, and a patient's significant other on prescribed diets and monitoring adherence and response to diet therapy. Correctional institutions shall not be required to provide counseling to family members or significant others;

(E) referring a patient for assistance with nutrition resources such as financial assistance, community resources or in-home assistance;

(F) participating in continuous quality improvement activities; and

(G) providing ongoing monitoring of subjective and objective data to determine the need for timely intervention and follow-up. Measurement criteria include but are not limited to weight changes, blood chemistries, adequacy of dialysis,and medication changes which affect nutrition status and potentially cause adverse nutrient interactions.

(3) The collection of objective and subjective data to assess nutrition status shall occur within two weeks or seven treatments from admission to the facility, whichever occurs later. A comprehensive nutrition assessment with an educational component shall be completed within 30 days or 13 treatments from admission to the facility, whichever occurs later.

(4) A nutrition reassessment shall be conducted annually or more often if indicated.

(5) Each facility shall employ or contract with a dietitian(s) to provide clinical nutrition services for each patient. One full-time equivalent of dietitian time shall be available for up to 100 patients with the maximum patient load per full-time equivalent of dietitian time being 150 patients.

(6) Nutrition services shall be available at the facility during scheduled treatment times. Access to services may require an appointment.

(i) Social services.

(1) Social services shall be provided to patients and their families and shall be directed at supporting and maximizing the adjustment, social functioning, and rehabilitation of the patient.

(2) The social worker shall be responsible for:

(A) conducting psychosocial evaluations;

(B) participating in team review of patient progress;

(C) recommending changes in treatment based on the patient's current psychosocial needs;

(D) providing case work and group work services to patients and their families in dealing with the special problems associated with end stage renal disease;

(E) except in the case of social workers providing service in correctional institutions, identifying community social agencies and other resources and assisting patients and families to utilize them; and

(F) participating in continuous quality improvement activities.

(3) Initial contact between the social worker and the patient shall occur and be documented within two weeks or seven treatments from the patient's admission, whichever occurs later. A comprehensive psychosocial assessment shall be completed within 30 days or 13 treatments from the patient's admission, whichever occurs later.

(4) A psychosocial reassessment shall be conducted annually or more often if indicated.

(5) Each facility shall employ or contract with a social worker(s) to meet the psychosocial needs of the patients.

(6) Social services shall be available at the facility during the times of patient treatment. Access to social services may require an appointment.

(j) Medical services.

(1) Medical director. The medical director is responsible for:

(A) developing facility treatment goals which are based on review of aggregate data assessed through quality management activities;

(B) assuring adequate training of licensed nurses and dialysis technicians;

(C) adequate monitoring of patients and the dialysis process; and

(D) developing and implementing all policies required by this chapter.

(2) Medical staff.

(A) Each patient shall be under the care of a physician on the medical staff.

(B) The care of a pediatric dialysis patient shall be in accordance with this subparagraph. If a pediatric nephrologist is not available as the primary physician, an adult nephrologist may serve as the primary physician with direct patient evaluation by a pediatric nephrologist according to the following schedule:

(i) for patients two years of age or younger - monthly (two of three evaluations may be by phone);

(ii) for patients three to 12 years of age - quarterly; and

(iii) for patients 13 to 18 years of age - semiannually.

(C) At a minimum, each patient receiving dialysis in the facility shall be seen by a physician on the medical staff once every two weeks; home patients shall be seen at least every three months. There shall be evidence of monthly assessment for new and recurrent problems and review of dialysis adequacy.

(D) A physician on the medical staff shall be on call and available 24 hours a day (in person or by telecommunication) to patients and staff.

(E) Orders for treatment shall be in writing and signed by the prescribing physician. Routine orders for treatment shall be updated at least annually. Orders for treatment shall include treatment time, dialyzer, blood flow rate, target weight, medications including heparin, and specific infection control measures as needed.

(F) If advanced practice nurses or physician assistants are utilized:

(i) there shall be evidence of communication with the treating physician whenever the advanced practice nurse or physician assistant changes treatment orders;

(ii) the advanced practice nurse or physician assistant may not replace the physician in participating in patient care planning or in quality management activities; and

(iii) the treating physician shall be notified and direct the care of patient medical emergencies.

(k) Home dialysis (self dialysis).

(1) If a facility provides self dialysis training, a registered nurse with at least 12 months experience in the applicable dialysis modality (hemodialysis or peritoneal dialysis) shall be responsible for training the patient or family. When other personnel assist in the training, supervision by the registered nurse shall be demonstrated.

(2) For a patient who performs self dialysis at home, the following services shall be provided:

(A) a yearly physical examination;

(B) monthly contact from facility staff by telephone calls or clinic visits;

(C) a clinic visit at least every three months;

(D) communication with the appropriate interdisciplinary team member(s);

(E) routine laboratory work according to facility policy; and

(F) a mechanism to contact staff at any time in the event of an emergent need.

(3) The facility shall provide directly or under arrangement the following services.

(A) For hemodialysis, the required services are:

(i) surveillance of the patient's home adaptation, including provisions for visits to the home;

(ii) consultation for the patient with a registered nurse, social worker and a dietitian;

(iii) a record keeping system which assures continuity of care;

(iv) installation and maintenance of equipment;

(v) testing and appropriate treating of the water used for dialysis; and

(vi) ordering of supplies on an ongoing basis.

(B) For continuous ambulatory peritoneal dialysis, the required services are:

(i) consultation for the patient with a registered nurse, a social worker and a dietitian;

(ii) a record keeping system which assures continuity of care; and

(iii) ordering of supplies on an ongoing basis.

(C) For continuous cycling peritoneal dialysis, the required services are:

(i) surveillance of the patient's home adaptation, including provisions for visits to the home;

(ii) consultation for the patient with a registered nurse, a social worker and a dietitian;

(iii) a record keeping system which assures continuity of care;

(iv) installation and maintenance of equipment; and

(v) ordering of supplies on an ongoing basis.

(l) Laboratory services. A facility that provides laboratory services shall comply with the requirements of Federal Public Law 100-578, Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988). CLIA 1988 applies to all facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(m) Illegal remuneration prohibited. A facility shall not violate the Health and Safety Code, §161.191, et. seq. relating to the prohibition on illegal remuneration for the purpose of securing or soliciting patients or patronage.

(n) Do-not-resuscitate orders. The facility shall comply with the Health and Safety Code, Chapter 674 relating to out-of-hospital do-not-resuscitate orders. §117.44. Qualifications of Staff.

§117.44. Qualifications of Staff.

(a) General.

(1) A written orientation program to familiarize all new employees (including office staff) with the facility, its policies, and job responsibilities shall be developed and implemented.

(2) In order to assure that each new direct patient care staff member is provided sufficient time to become familiar with the facility, the orientation program provided by the facility shall be a minimum time of two weeks for individuals with previous dialysis experience. For new direct patient care staff members with no previous dialysis experience, the orientation program shall be two weeks plus additional orientation time as determined by the facility.

(3) A facility shall provide registered nurses with no previous dialysis experience an orientation program of a minimum of six weeks. For these registered nurses, the six-week orientation program shall contain at least the following subject content specific to the management of the end stage renal disease patient and appropriate to the population served by the facility:

(A) fluid, electrolyte and acid-base balance;

(B) kidney disease and treatment;

(C) dietary management of kidney disease;

(D) principles of dialysis;

(E) dialysis technology;

(F) venipuncture technique;

(G) care of the dialysis patient;

(H) psychological, social, financial, and physical complications of long-term dialysis;

(I) prevention of hepatitis and other infectious diseases; and

(J) risks and benefits of reuse (if reuse is practiced).

(4) Each licensed nurse and dialysis technician shall demonstrate competency through written and skills testing annually. Evidence of competency shall be documented in writing and maintained in personnel files.

(5) A facility shall maintain documentation to demonstrate that each staff member providing patient care completes at least five hours of continuing education related to end stage renal disease annually. Continuing education may be provided by facility staff.

(b) Medical staff.

(1) Each physician on the medical staff shall have a current license to practice medicine in the State of Texas.

(2) The governing body of a facility shall designate a medical director.

(3) The members of the medical staff may include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients.

(4) If an advanced practice nurse or physician assistant is utilized, such individuals shall meet the requirements established by the Board of Nurse Examiners (for an advanced practice nurse) or the Board of Medical Examiners (for a physician assistant).

(c) Nursing staff.

(1) Each licensed nurse shall have a current Texas license to practice nursing.

(2) Each nurse assigned charge responsibilities shall be a registered nurse and have six months experience in hemodialysis obtained within the last 24 months. An RN who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the six months experience in dialysis obtained within the last 24 months. The responsibilities of the charge nurse shall include:

(A) making daily assignments based on patient needs;

(B) providing immediate supervision of direct patient care;

(C) making patient assessments when indicated; and

(D) communicating with the physician(s), social worker(s) and dietitian(s).

(3) The following provisions create an exception to the requirement that the charge nurse be a registered nurse.

(A) A licensed vocational nurse employed in a facility as of September 1, 1996, and who has two years full time experience as a charge nurse in a facility prior to September 1, 1996, may continue to function as a charge nurse for a facility.

(B) A licensed vocational nurse with two years full time experience in dialysis may function as a charge nurse in the temporary absence of the charge nurse at the facility.

(C) If a licensed vocational nurse is functioning as a charge nurse, in order to provide the direct supervision of dialysis technicians required by the statute, the facility's full time supervising nurse shall establish written protocols addressing the supervision of the technicians. The implementation of the protocol shall be considered to constitute direct supervision of the technicians by the RN. In the alternative, an RN who is the instructor of the facility's

dialysis technician course, another RN, or a physician may provide onsite, direct supervision of the dialysis technicians.

(D) This paragraph expires on September 1, 1999.

(4) If patient self-care training is provided, a registered nurse who has at least 12 months experience in dialysis and experience in the applicable dialysis modality shall be responsible for training the patient or family. When other personnel assist in the training, supervision by the registered nurse shall be demonstrated.

(d) Nutritional staff. Each dietitian shall be licensed in Texas, be eligible for registration by the Commission on Dietetic Registration of the American Dietetic Association, and have one year of experience in clinical dietetics after becoming eligible for registration.

(e) Social services staff. Each social worker shall:

(1) be licensed as a social worker under the Human Resources Code, Chapter 50, and hold a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or

(2) have worked for at least two years as a social worker, one year of which was in a dialysis facility or transplantation program prior to September 1, 1976, and have established a consultative relationship with a social worker who has a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education.

(f) Staff responsible for the water treatment system.

(1) Facility staff responsible for the water treatment system shall demonstrate understanding of the risks to patients of exposure to water which has not been treated so as to remove contaminants and impurities. Documentation of training to assure safe operation of the water treatment system shall be maintained for each individual responsible for the operation of the system.

(2) Only individuals qualified by training, education, or experience may repair or replace components of the water treatment system. Documentation of such training to qualify these persons shall be maintained on file in the facility.

(g) Staff responsible for equipment maintenance and repair. Staff providing equipment maintenance and repair shall have successfully completed a training course and demonstrated competency in providing maintenance and repair for the equipment being serviced. The training course shall include at least the following components:

(1) prevention of transmission of hepatitis through dialysis equipment;

(2) safety requirements of dialysate delivery systems;

(3) bacteriologic control;

(4) water quality standards; and

(5) repair and maintenance of dialysis and other equipment in use.

§117.45. Clinical Records.

(a) A facility shall establish and maintain a clinical record system to assure that the care provided to each patient is completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(1) All information shall be centralized in the patient's clinical record and be protected against loss or damage.

(2) The facility shall provide an area for clinical records storage which is separate from all patient treatment areas. The clinical records area shall have adequate space for reviewing, dictating, sorting, or recording records. If electronic imaging devices are employed (i.e., microfilm or optical disc), the clinical records area shall have adequate space for transcribing records in the electronic format. The facility shall store the active clinical record of each patient currently treated by the facility on site.

(3) The facility shall ensure that each patient's personal and medical records are treated with confidentiality.

(4) Signature stamps may not be used to authenticate medical record entries.

(5) Computerized records shall meet all requirements of paper records including protection from casual access and retention for the specified period. Systems shall assure that entries regarding the delivery of care may not be altered without evidence and explanation of such alteration.

(6) Inactive clinical records may be preserved on microfilm, optical disc or other electronic means and may be stored off-site as long as security is maintained and the record is readily retrievable for review by the department or the department's designee.

(7) Each clinical record shall include:

(A) identifying information;

(B) consents and notifications;

(C) physician orders;

(D) progress notes;

(E) problem list;

(F) medical history and physical;

(G) professional assessments by the registered nurse, social worker, and dietitian;

(H) medication record to include medications given during treatment (which may be listed on the treatment record) and a listing of medications the patient takes at home;

(I) transfusion record;

(J) laboratory reports;

(K) diagnostic studies;

(L) hospitalization records;

(M) consultations;

(N) record of creation and revision of access for dialysis;

(O) patient care plans, including evidence of team review and adjustment;

(P) evidence of patient education;

(Q) daily treatment records; and

(R) discharge summary, if applicable.

(b) A patient's medical history and physical shall be completed 30 days before or within two weeks after admission to the facility. Prior to the first treatment in the facility, the physician shall inform the charge nurse of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The clinical record shall include this data.

(c) Progress notes shall provide an accurate picture of the progress of the patient, reflecting changes in patient status, plans for and results of changes in treatment, diagnostic testing, consultations, and unusual events. Each of the interdisciplinary team members shall record the progress of the patient as indicated by any change in the patient's medical, nutritional, or psychosocial condition or at least every six months.

(d) The patient's condition and response to treatment shall be noted on the daily treatment record.

(e) Clinical records of transient patients shall include, at a minimum, orders for treatment in this facility, laboratory reports performed within a month of treatment at this facility including hepatitis B antigen status, the most current patient care plan and treatment records from the home facility, and records of care and treatment at this facility.

(f) Clinical records shall be completed within 30 days after discharge. The discharge summary shall clearly identify the disposition of the patient and include the diagnosis or cause of death, date of discharge or death, location of death, transplant or relocation information when appropriate, and reason for discharge if not for transplantation or death.

(g) Clinical records are the property of the facility and shall not be removed from the premises except by subpoena or court order, or for protection in disaster situations,except as described in subsection (a)(6) of this section.

(h) Copies of pertinent portions of a patient's record shall be provided when the patient is transferred. The records provided shall include, at a minimum, the most current orders for dialysis treatment, the last three treatment records, the current hepatitis status, and the most current patient care plan. If the patient is transferred to another outpatient facility, copies of the most recent history and physical and assessment of each member of the interdisciplinary team shall also be provided.

(i) Original records shall be retained by a facility for a minimum of five years after the discharge of the patient. The facility may not destroy clinical records that relate to any matter that is involved in litigation if the facility knows the litigation has not been finally resolved.

(j) If a facility ceases operation, there shall be an arrangement for the preservation of records to insure compliance with this section. The facility shall send the department written notification of the location of the clinical records and the name and address of the clinical records custodian.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 16, 1996.

TRD-9612065
Susan K. Steeg
General Counsel
Texas Department of Health
Effective date: September 6, 1996
Proposal publication date: April 12, 1996
For further information, please call: (512) 458–7236

♦ ♦ ♦

Subchapter E. Dialysis Technicians

25 TAC §§117.61–117.65

The new rules are adopted under the Health and Safety Code, §251.003 which provides the board with authority to adopt rules to implement the statute, including requirements regarding the issuance, renewal, denial, suspension, and revocation of an ESRD license; §251.014 regarding minimum standards for the protection of the health and safety of an ESRD facility patient, including the qualifications and supervision of the professional staff (including physicians) and other personnel, the equipment used by the facility, the sanitary and hygienic conditions in the facility, quality assurance for patient care, the provision and coordination of treatment and services by the facility, clinical records maintained by the facility, design and space requirements for safe access and ensuring patient privacy, indicators of quality of care, and water treatment and reuse by the facility; and §251.032 regarding minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians, the determination of the competency of individuals who have been trained as dialysis technicians, and the acts and practices that are allowed or prohibited for dialysis technicians; and under Health and Safety Code, §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department and the commissioner of health.

§117.62. Training Curricula and Instructors.

(a) Specific objectives for training curricula. Each training program for dialysis technicians shall develop a written curriculum with objectives specified for each section.

(b) Components of training curricula. The training curricula for dialysis technicians shall include the following minimum components:

(1) introduction to dialytic therapies to include history and major issues as follows:

(A) history of dialysis;

(B) definitions and terminology;

(C) communication skills;

(D) ethics and confidentiality;

(E) multidisciplinary process;

(F) roles of other team members; and

(G) information about renal organizations and resources;

(2) principles of hemodialysis to include:

(A) principles of dialysis;

(B) access to the circulatory system; and

(C) anticoagulation, local anesthetics, and normal saline;

(3) understanding the individual with kidney failure to include:

(A) basic renal anatomy, physiology, and pathophysiology;

(B) the effect of renal failure on other body systems;

(C) symptoms and findings related to the uremic state;

(D) modes of renal replacement therapy, including transplantation;

(E) basic renal nutrition;

(F) basic psychosocial aspects of end stage renal disease (ESRD);

(G) medications commonly administered to patients with ESRD;

(H) confidentiality of patient personal and clinical records;

(I) professional conduct;

(J) patient rights and responsibilities; and

(K) rehabilitation;

(4) dialysis procedures to include:

(A) using aseptic technique;

(B) technical aspects of dialysis, operation and monitoring of equipment, initiation and termination of dialysis;

(C) delivering an adequate dialysis treatment and factors which may result in inadequate treatment;

(D) observing and reporting patient reactions to treatment;

(E) glucose monitoring and hemoglobin/hematocrit monitoring;

(F) emergency procedures and responses such as cardiopulmonary resuscitation, air embolism management, and response to line separation and hemolysis;

(G) external and internal disasters, fire, natural disasters, and emergency preparedness; and

(H) safety, quality control, and continuous quality improvement;

(5) hemodialysis devices to include:

(A) theory and practice of conventional, high efficiency, and high flux dialysis;

(B) dialysate composition, options, indications, complications, and safety;

(C) monitoring and safety; and

(D) disinfection of equipment;

(6) water treatment to include:

(A) standards for water treatment used for dialysis as described in the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the American Association for the Advancement of Medical Instrumentation (AAMI), 3330 Washington Boulevard, Suite 400, Arlington, Virginia 22201;

(B) systems and devices;

(C) monitoring; and

(D) risks to patients of unsafe water;

(7) reprocessing, if the facility practices reuse, to include:

(A) principles of reuse;

(B) safety, quality control, universal precautions, and water treatment; and

(C) standards for reuse as described in the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI;

(8) patient teaching to include:

(A) the role of the technician in supporting patient education goals; and

(B) adult education principles;

(9) infection control and safety to include:

(A) risks to patients of nosocomial infections, accidents, and errors in treatment;

(B) universal precautions, aseptic technique, sterile technique, and specimen handling;

(C) basic bacteriology and epidemiology;

(D) risks to employees of blood and chemical exposure; and

(E) electrical, fire, disaster, environmental safety, and hazardous substances; and

(10) quality assurance and continuous quality improvement (QA/CQI) to include:

(A) role of the technician in quality assurance activities;

(B) principles of QA/CQI; and

(C) the importance of ongoing quality control activities in assuring safe dialysis treatments are provided to patients.

(c) Additional responsibilities.

(1) If a dialysis technician is to assist with training or treatment of peritoneal dialysis patients, the following content must also be included:

(A) principles of peritoneal dialysis;

(B) sterile technique;

(C) peritoneal dialysis delivery systems;

(D) symptoms of peritonitis; and

(E) other complications of peritoneal dialysis.

(2) If a dialysis technician, other than a licensed vocational nurse (LVN), is to cannulate access or administer normal saline, heparin, or lidocaine, the following content must be included:

(A) access to the circulation to include:

(i) fistula: creation, development, needle placement, and prevention of complications;

(ii) grafts: materials used, creation, needle placement, and prevention of complications; and

(iii) symptoms to report;

(B) safe administration of medications to include:

(i) identifying the right patient;

(ii) assuring the right medication;

(iii) measuring the right dose;

(iv) ascertaining the right route; and

(v) checking the right time for administration;

(C) administration of normal saline to include:

(i) reasons for administration;

(ii) potential complications;

(iii) administration limits; and

(iv) information to report and record;

(D) administration of heparin to include:

(i) reasons for administration;

(ii) methods of administration;

(iii) preparation of ordered dose;

(iv) potential complications; and

(v) information to report and record; and

(E) administration of lidocaine to include:

(i) reasons for administration;

(ii) method of administration;

(iii) preparation of ordered dose;

(iv) potential complications and risks; and

(v) information to report and record.

(d) Roster. A roster of attendance for each training class shall be maintained by the instructor.

(e) Trainee evaluation. Each trainee shall be evaluated on a weekly basis during the training program to ascertain the trainee's progress.

(f) Written examination. The dialysis technician trainee shall complete a written examination. The examination shall encompass the content required in subsection (b) of this section. If the dialysis technician trainee will cannulate access and administer medications, the examination shall encompass the content described in subsection (c) of this section. A score of 80% is required on the written examination(s) covering the required content. Current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.

(g) Instructors. An instructor for the course to train an individual as a dialysis technician shall be:

(1) a physician who qualifies as a medical director;

(2) a registered nurse with at least 12 months of experience in hemodialysis obtained within the last 24 months and a current competency skills checklist on file in the facility or a registered nurse instructor of a dialysis technician training course of an accredited college or university; or

(3) a qualified dietitian or social worker providing training only within the person's area of expertise.

(h) Preceptors. Licensed nurses and patient care technicians who have a least one year of experience in hemodialysis and a current competency skills checklist on file in the facility may assist in didactic sessions and serve as preceptors.

(i) Length of training. For persons with no previous experience in direct patient care, a minimum of 80 clock hours of classroom education and 200 clock hours of directly supervised clinical training shall be required. Training programs for dialysis technician trainees who have previous direct patient care experience may be shortened if competency with the required knowledge and skills is demonstrated, but may not be less than a total of 80 clock hours of combined classroom education and clinical training.

§117.63. Competency Evaluation.

(a) Each facility shall appoint a training review committee to consist of at least the medical director, supervising nurse, chief technician, and administrator. This committee shall review the training records of each trainee, including tests and skills checklists, hear comments from the training instructor(s) and preceptor(s), and validate that the trainee has successfully completed the training program.

(b) An individual who completed the facility's orientation program and was determined by the facility to be qualified to deliver dialysis patient care before September 1, 1996, may qualify as a dialysis technician by passing the written examination described in §117.62(f) of this title (relating to Training Curricula and Instructors) and demonstrating competency by completion of the skills checklist described in subsection (c) of this section. Current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.

(c) The supervising nurse or a registered nurse who qualifies as an instructor under §117.62(e)(2) of this title shall complete a competency skills checklist to document each dialysis technician trainee's knowledge and skills for the following allowed acts:

(1) assembling necessary supplies;

(2) preparing dialysate according to procedure and dialysis prescription;

(3) assembling and preparing the dialysis extracorporeal circuit correctly;

(4) securing the correct dialyzer for the specific patient;

(5) installing and rinsing dialyzer and all necessary tubing;

(6) testing monitors and alarms, conductivity, and (if applicable) presence and absence of residual sterilants;

(7) setting monitors and alarms according to facility and manufacturer protocols;

(8) obtaining predialysis vital signs, weight, and temperature according to facility protocol and informing the registered nurse of unusual findings;

(9) inspecting access for patency and, after cannulation is performed and heparin administered, initiating dialysis according to the patient's prescription, observing universal precautions, and reporting unusual findings to the registered nurse;

(10) adjusting blood flow rates according to established protocols and the patient's prescription;

(11) calculating and setting the dialysis machine to allow fluid removal rates according to established protocols and the patient's prescription;

(12) monitoring the patient and equipment during treatment, responding appropriately to patient needs and machine alarms, and reporting unusual occurrences to the registered nurse;

(13) changing fluid removal rate, placing patient in Trendelenburg position, and administering replacement normal saline as directed by the registered nurse, physician order, or facility protocol;

(14) documenting findings and actions per facility protocol;

(15) describing appropriate response to dialysis-related emergencies such as cardiac or respiratory arrest, needle displacement or infiltration, clotting, blood leaks, or air emboli and to nonmedical emergencies such as power outages or equipment failure;

(16) discontinuing dialysis and establishing hemostasis:

(A) inspecting, cleaning, and dressing access according to facility protocol; and

(B) reporting unusual findings and occurrences to the registered nurse;

(17) obtaining and recording post dialysis vital signs, temperature, and weight and reporting unusual findings to the registered nurse;

(18) discarding supplies and sanitizing equipment and treatment chair according to facility protocol;

(19) communicating the patient's emotional, medical, psychological, and nutritional concerns to the registered nurse;

(20) obtaining current certification in cardiopulmonary resuscitation; and

(21) maintaining professional conduct, good communication skills, and confidentiality in the care of patients.

(d) For dialysis technician trainees who will be assisting with training or treatment of peritoneal dialysis patients, the following checklist shall be completed satisfactorily:

(1) assisting patients in ordering supplies;

(2) making a dialysate exchange (draining and refilling the peritoneal space with dialysate) to include continuous ambulatory peritoneal dialysis exchange procedures and initiation or discontinuation of continuous cycling peritoneal dialysis;

(3) observing peritoneal effluent;

(4) knowing what observations to report;

(5) collecting dialysate specimen;

(6) performing a transfer tubing change; and

(7) setting up and operating continuous cycling peritoneal dialysis equipment.

(e) For dialysis technician trainees who will be cannulating dialysis access and administering heparin and normal saline, the following checklist shall also be completed satisfactorily:

(1) cannulation to include:

(A) inspecting the access for patency;

(B) preparing the skin;

(C) using aseptic technique;

(D) placing needles correctly;

(E) establishing blood access;

(F) replacing needles;

(G) knowing when to call for assistance; and

(H) securing needles;

(2) administration of heparin to include:

(A) checking the patient's individual prescription;

(B) preparing the dose;

(C) labeling the prepared syringe;

(D) administering the dose; and

(E) observing for complications;

(3) administration of normal saline to include:

(A) understanding unit protocol;

(B) checking the patient's prescription;

(C) recognizing signs of hypotension;

(D) notifying the registered nurse;

(E) administering normal saline; and

(F) rechecking vital signs; and

(4) administration of lidocaine to include:

(A) checking the patient's prescription;

(B) identifying the correct vial of medication;

(C) preparing the dose;

(D) administering the dose; and

(E) observing for complications.

(f) If a dialysis technician other than an LVN is to cannulate a dialysis access or administer normal saline, heparin or lidocaine, the medical director shall verify and document competency of the dialysis technician to perform these tasks and delegate authority to the technician in accordance with the Medical Practice Act, Article 4495b, §3.06(d).

§117.65. Prohibited Acts.

(a) Performance of the following acts by any dialysis technician who is not a licensed vocational nurse qualified as a charge nurse is prohibited:

(1) initiation of patient education; or

(2) alteration of ordered treatment, including shortening of the treatment time.

(b) Performance of the following acts by a dialysis technician who is not a licensed vocational nurse is prohibited:

(1) initiation of dialysis via a central catheter;

(2) administration of medications other than normal saline, heparin or lidocaine, which may only be administered in the course of a routine dialysis treatment;

(3) administration of blood or blood products;

(4) performance of non-access site venipuncture;

(5) performance of arterial puncture;

(6) acceptance of physician orders; or

(7) provision of hemodialysis treatment to pediatric patients under 14 years of age or under 35 kilograms.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 16, 1996.

TRD-9612066
Susan K. Steeg
General Counsel
Texas Department of Health
Effective date: September 6, 1996
Proposal publication date: April 12, 1996
For further information, please call: (512) 458–7236

♦ ♦ ♦

Subchapter F. Enforcement

25 TAC §§117.81–117.85

The new rules are adopted under the Health and Safety Code, §251.003 which provides the board with authority to adopt rules to implement the statute, including requirements regarding the issuance, renewal, denial, suspension, and revocation of an ESRD license; §251.014 regarding minimum standards for the protection of the health and safety of an ESRD facility patient, including the qualifications and supervision of the professional staff (including physicians) and other personnel, the equipment used by the facility, the sanitary and hygienic conditions in the facility, quality assurance for patient care, the provision and coordination of treatment and services by the facility, clinical records maintained by the facility, design and space requirements for safe access and ensuring patient privacy, indicators of quality of care, and water treatment and reuse by the facility; and §251.032 regarding minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians, the determination of the competency of individuals who have been trained as dialysis technicians, and the acts and practices that are allowed or prohibited for dialysis technicians; and under Health and Safety Code, §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department and the commissioner of health.

§117.81. Corrective Action Plan.

(a) Medical review board. The medical review board (MRB) may assist the Texas Department of Health (department) in determining the corrective action required when the results of an inspection or an annual report indicate that significant problems potentially impacting patient outcomes exist.

(1) At the conclusion of an on-site inspection, the department may refer a facility to the MRB if the results of the inspection present concerns related to patient outcomes.

(2) The MRB will review data from facilities' annual reports and identify to the department facilities with potential quality issues. These facilities may be requested to provide additional information or may be subject to an on-site inspection, corrective action plan or enforcement action.

(b) Corrective action plan. A corrective action plan may be used in accordance with §251.061 of the statute. This subsection is consistent with §251.061 of the statute.

(1) The department may use a corrective action plan as an alternative to enforcement action under the statute.

(2) Before taking enforcement action, the department shall consider whether the use of a corrective action plan is appropriate. In determining whether to use a corrective action plan, the department shall consider whether:

(A) the facility has violated the statute or this chapter and the violation has resulted in a adverse patient result;

(B) the facility has a previous history of lack of compliance with the statute, this chapter or a previously executed corrective action plan; or

(C) the facility fails to agree to a corrective action plan.

(3) The department may use a level one, level two, or level three corrective action plan, as determined by the department in accordance with this subsection, after inspection of the facility.

(A) If deficiencies are identified after an inspection, the surveyor may request a corrective action plan. The surveyor shall identify the level of corrective action plan required.

(B) The facility shall develop and implement a corrective action plan approved by the department. The facility shall provide the corrective action plan within the time frames specified by the department. A corrective action plan shall identify dates by which compliance will be accomplished. The dates by which compliance will be accomplished on a corrective action plan shall not exceed 45 days from the date the deficiency is cited.

(C) The department shall review and approve the corrective action plan. If the corrective action plan is not acceptable, the department shall notify the facility of changes needed in order for the department to approve the plan.

(D) The facility shall come into compliance within the time frames set out in the corrective action plan.

(E) The department shall verify the correction of deficiencies by mail or on-site inspection.

(F) Acceptance of a corrective action plan does not preclude the department from taking other enforcement action as appropriate under this subchapter.

(4) A level one corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter, but the circumstances are not serious or life-threatening. The department or a monitor may supervise the implementation of the plan.

(5) A level two corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter and the circumstances are potentially serious or life-threatening or if the department finds that the facility failed to implement or comply with a level one corrective action plan. The department or a monitor shall supervise the implementation of the plan. Supervision of the implementation of the plan may include on-site supervision, observation, and direction.

(6) A level three corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter and the circumstances are serious or life-threatening or if the department finds that the facility failed to comply with a level two corrective action plan or to cooperate with the department in connection with that plan. In connection with requiring a level three corrective action plan, the department may seek the appointment of a temporary manager under §117.82 of this title (relating to Appointment of a Temporary Manager).

(7) A corrective action plan is not confidential. Information contained in the plan may be excepted from required disclosure under the Government Code, Chapter 552 or other applicable law.

(8) The department shall select the monitor for a corrective action plan. The monitor shall be an individual or team of individuals and may include a professional with end stage renal disease experience or a member of the MRB.

(A) The monitor may not be or include individuals who are current or former employees of the facility that is the subject of the corrective action plan or of an affiliated facility.

(B) The purpose of the monitor is to observe, supervise, consult, and educate the facility and the employees of the facility under a corrective action plan.

(C) The facility shall pay the cost of the monitor.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 16, 1996.

TRD-9612067
Susan K. Steeg
General Counsel
Texas Department of Health
Effective date: September 6, 1996
Proposal publication date: April 12, 1996
For further information, please call: (512) 458–7236

♦ ♦ ♦

TITLE 31. NATURAL RESOURCES AND CONSERVATION

Part II. Texas Parks and Wildlife Department

Chapter 59. Parks

The Texas Parks and Wildlife Commission, in a regularly scheduled meeting held July 11, 1996, adopted the repeals of §§59.131-59.136 and new §§59.131-59.136, concerning State Park Rules, without changes to the text as published in the June 7, 1996, issue of the *Texas Register* (21 TexReg 5148).

The repeals and new rules represent simplification, clarification and reduction of existing state park rules. This action was taken as part of the Parks and Wildlife Commission regulations sunset process.

The repeals and new rules set into place rules which regulate activities in Texas State Parks.

No comments were received regarding adoption of the repeals and new rules.

State Park Rules

31 TAC §§59.131–59.136

The repeals are adopted under Parks and Wildlife Code, §13.101 which provides the commission authority to promulgate regulations governing the health, safety, and protection of persons and property on lands under the control of the department.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 19, 1996.

TRD-9612115
Bill Harvey
Regulatory Coordinator
Texas Parks and Wildlife Department
Effective date: September 9, 1996
Proposal publication date: June 7, 1996
For further information, please call: (512) 389-4642

State Park Operational Rules

31 TAC §§59.131-59.136

The new sections are adopted under Parks and Wildlife Code, §13.101 which provides the commission authority to promulgate regulations governing the health, safety, and protection of persons and property on lands under the control of the department.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on August 19, 1996.

TRD-9612114
Bill Harvey
Regulatory Coordinator
Texas Parks and Wildlife Department

Effective date: September 9, 1996
Proposal publication date: June 7, 1996
For further information, please call: (512) 389-4642

Part XV. Texas Low-Level Radioactive Waste Disposal Authority

Chapter 449. General Provisions

Subchapter H. Training and Education for Employees

31 TAC §§449.91-449.93

The Texas Low-Level Radioactive Waste Disposal Authority adopts new Subchapter H, Training and Education for Employees, to §§449.91-449.93 concerning training and education for employees of the authority, without changes to the proposed text as published in the June 25, 1996, issue of the *Texas Register* (21 TexReg 5848).

No comments were received in response to the published rule.

The new subchapter is adopted under the Health and Safety Code, §402.054 which provides the Texas Low-Level Radioactive Waste Disposal Authority with the authority to adopt rules, standards, and orders necessary to properly carry out the Texas Low-Level Radioactive Waste Disposal Authority Act, and Texas Government Code §§656.041-.049, which requires agencies to adopt employee training and education rules.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

Issued in Austin, Texas, on August 19, 1996.

TRD-9612124
Lee H. Mathews
Deputy General Manager and General Counsel
Texas Low-Level Radioactive Waste Disposal Authority
Effective date: September 9, 1996
Proposal publication date: June 25, 1996
For further information, please call: (512) 451-5292

♦ ♦ ♦

OPEN MEETINGS

Agencies with statewide jurisdiction must give at least seven days notice before an impending meeting. Institutions of higher education or political subdivisions covering all or part of four or more counties (regional agencies) must post notice at least 72 hours before a scheduled meeting time. Some notices may be received too late to be published before the meeting is held, but all notices are published in the ***Texas Register***.

Emergency meetings and agendas. Any of the governmental entities listed above must have notice of an emergency meeting, an emergency revision to an agenda, and the reason for such emergency posted for at least two hours before the meeting is convened. All emergency meeting notices filed by governmental agencies will be published.

Posting of open meeting notices. All notices are posted on the bulletin board at the main office of the Secretary of State in lobby of the James Earl Rudder Building, 1019 Brazos, Austin. These notices may contain a more detailed agenda than what is published in the ***Texas Register***.

Meeting Accessibility. Under the Americans with Disabilities Act, an individual with a disability must have an equal opportunity for effective communication and participation in public meetings. Upon request, agencies must provide auxiliary aids and services, such as interpreters for the deaf and hearing impaired, readers, large print or braille documents. In determining type of auxiliary aid or service, agencies must give primary consideration to the individual's request. Those requesting auxiliary aids or services should notify the contact person listed on the meeting summary several days prior to the meeting by mail, telephone, or RELAY Texas (1-800-735-2989).

State Office of Administrative Hearings

Monday, September 9, 1996, 1:00 p.m.

7800 Shoal Creek Boulevard

Austin

Utility Division

AGENDA:

A Hearing on the Merits will be held at the above date and time in SOAH DOCKET NO. 473–96–0705–COMPLAINT OF GAS SERVICES, INC., AGAINST SOUTHWESTERN BELL TELEPHONE COMPANY, INC. (PUC DOCKET NO. 15630)

Contact: J. Kay Trostle, 300 West 15th Street, Suite 502, Austin, Texas 78701–1649, (512) 936–0728
Filed: August 23, 1996, 2:55 p.m.

TRD-9612379

♦ ♦ ♦

Texas Aerospace Commission

Thursday, August 29, 1996, 9:00 a.m.

2nd Floor Conference Room, Robert Mueller Airport

Austin

Board of Directors

AGENDA:

Welcome and Call to Order

Approval of Last Meeting Minutes

Executive Session; Final Selection of TAC Executive Director

Status Report from Larry Griffin

Travel Voucher Instructions

Lunch-Tentative Visit to New Office Space in Stephen F. Austin Building, B-60

Old Business

New Business

Commissioner's Open Forum

Summary of Outstanding Action Items

Adjournment

Contact: Amy Kennedy-Reynolds, Nasa Johnson Space Center, 2101 Nasa Road One, MC-AP4, Houston, Texas 77058, (713) 483–6827.
Filed: August 21, 1996, 4:54 p.m.

TRD-9612247

♦ ♦ ♦

Texas Commission on Alcohol and Drug Abuse (TCADA)

Monday, September 9, 1996, 11:00 a.m.

3930 Kirby, Suite 207, Texas Youth Commission

Houston

Regional Advisory Consortium (RAC), Region 6

AGENDA:

Call to Order, welcome and introductions of members and guests; approval of minutes; membership issues; review of regional funding and commission presentation; discussion period; new business; public comment; adjournment.

Contact: Heather Harris, TCADA, 710 Brazos, Austin, Texas 78701, (512) 867–6319.
Filed: August 23, 1996, 4:08 p.m.

TRD-9612410

♦ ♦ ♦

Texas Bond Review Board

Monday, September 9, 1996, 10:00 a.m.

300 West 15th Street, Committee Room 5, Clements Building, 5th Floor

Austin

Public Hearing/Work Session

AGENDA:

I. Call to Order

II. Introductions

III. Welcoming Remarks

IV. Hear and discuss public comments regarding the Private Activity Bond Allocation Program

V. Adjourn

Contact: Albert L. Bacarisse, Executive Director, 300 West 15th Street, Suite 409, Austin, Texas 78701, (512) 463–1741.
Filed: August 22, 1996, 2:38 p.m.

TRD-9612268

♦ ♦ ♦

Advisory Commission on State Emergency Communications

Thursday, September 5, 1996, 2:00 p.m.

West Texas Regional Poison Center, 4815 Alameda

El Paso

Poison Center Coordinating Committee Meeting

AGENDA:

The Committee will Call the Meeting to Order and Recognize Guests; Hear Public Comment; Hear Reports, Discuss and take Committee Action, as Necessary; Approval of July 8, 1996 Meeting Minutes; Roundtable; Subcommittee Reports; A. Report of the Subcommittee on Operations, B. Report of the Medical Directors Subcommittee, C. Report of the Subcommittee on Education; Elect Officers; Phase II Update and Discussion; FY 97 Budget Discussion; A. Network Cost Savings, B. ACSEC Telecommunications, C. Other; Diverted Call Policy; Strategic Plan; Other Business; Set Next Meeting Date. Adjourn.

Contact: Velia Williams, ACSEC, 333 Guadalupe Street, Austin, Texas 78701 (512) 305–6933. Persons requests interpreter services for the hearing-and speech impaired should contact Velia Williams at (512) 305–6933 at least two working days prior to the meeting.
Filed: August 23, 1996, 11:25 a.m.

TRD-9612346

♦ ♦ ♦

Employees Retirement System of Texas

Wednesday, September 4, 1996, 1:30 p.m.

ERS Auditorium- ERS Building, 18th and Brazos

Austin

Board of Trustees

AGENDA:

1. Final Adoption of New Trustee Rule 34 TAC §73.39 Relating to Increase for Certain Annuitants

2. Approval of Submission of Fiscal Years 1998–1999 Legislative Appropriations Request

3. Consideration of Changes to the Universe of Eligible Stocks

4. Set Date of Next ERS Board of Trustees Meeting

5. Adjournment

Contact: William S. Nail, 18th and Brazos, Austin, Texas 78701, (512) 867–3336
Filed: August 21, 1996, 2:03 p.m.

TRD-9612219

♦ ♦ ♦

State Employee Charitable Campaign

Monday, September 9, 1996, 9:00 a.m.

Texas Capitol- Room E1.024

Austin

State Policy Committee- Legislative Subcommittee

AGENDA:

A. Review of August 13, 1996 Meeting Minutes

B. Review of legislative language recommendations

C. Development of final recommendation for the State Policy Committee

Contact: Mike Terry, 823 Congress, Suite 1103, Austin, Texas 78701, (512) 478–6601.
Filed: August 23, 1996, 7:29 a.m.

TRD-9612298

♦ ♦ ♦

Texas State Board of Registration for Professional Engineers

Wednesday, September 11, 1996, 9:30 a.m.

1917 IH35 South, Board Room

Austin

Ad Hoc Committee on Design/Build

AGENDA:

1. A.) Meeting called to Order by Committee Chair at 9:30 a.m.; B). Roll Call; C.) Welcome Visitors

2. Discuss input received at prior meetings.

3. Take input from public.

4. Discuss and establish a proposal for presentation to the full board.

5. Discuss closely related issues.

6. Adjourn

Contact: John R. Speed, 1917 IH35 South, Austin, Texas 78741, (512) 440–7723.
Filed: August 22, 1996, 9:55 a.m.

TRD-9612254

♦ ♦ ♦

Texas Higher Education Coordinating Board

Wednesday, September 4, 1996, 10:00 a.m.

Chevy Chase Office Complex, Building 1, Room 1.100, 7745 Chevy Chase Drive

Austin

Family Practice Residency Advisory Committee

AGENDA:

Approval of Summary Notes for May 8, 1996 meeting — Dr. Coleridge; Health Find Update — Ms. Laura Jordan, Center for Rural Health Initiatives; Update on Coordinating Board's Legislative Budget Board Hearing — Dr. David Wright; Faculty Development Center; Reallocation of remaining FPRP funds and Review of Program — Dr. William Mygdal; Statewide Preceptorship Program; Fiscal Year 1997 Budget Projection- Dr. Jack Haley; Rural Rotation Program — Dr. Lewis Foxhall; Northeast Community Hospital-Closure of Program — Dr. Coleridge; and other business.

Contact: Stacey Silverman, THECB, Health Affairs Division, P.O. Box 12788, Capitol Station; Austin, Texas 78711, (512) 483–6206.
Filed: August 26, 1996, 10:12 a.m.

TRD-9612468

♦ ♦ ♦

Texas House of Representatives

Thursday, September 5, 1996, 2:00 p.m.

Capitol Extension, 15th and Congress, Room E2.028

Austin

House Committee on Public Health

AGENDA:

I. Call to Order

II. Roll Call

III. New Business —Review medical schools' use of funds generated by their family practice programs

IV. Old Business

V. Adjournment

Contact: Laura Lawlor, House Committee on Public Health, P.O. Box 2910, Austin, Texas 78703, (512) 463–0806.
Filed: August 22, 1996, 3:42 p.m.

TRD-9612277

♦ ♦ ♦

Monday, September 16, 1996, 9:00 a.m.

McAllen City Hall, City Commission Room, Third Floor, 1300 South Houston Street

Austin

House Committee on Public Health

AGENDA:

I. Call to Order

II. Roll Call

III. New Business —Study the possibilities of improving access to health care for children.

IV. Old Business

V. Adjournment

Contact: Laura Lawlor, House Committee on Public Health, P.O. Box 2910, Austin, Texas 78703, (512) 463–0806.
Filed: August 22, 1996, 3:42 p.m.

TRD-9612276

♦ ♦ ♦

Wednesday, September 25, 1996, 9:00 a.m.

Lubbock City Council Chambers, 1625 13th Street

Lubbock

House Committee on Public Health

AGENDA:

I. Call to Order

II. Roll Call

III. New Business —Study the possibilities of improving access to health care for children.

IV. Old Business

V. Adjournment

Contact: Laura Lawlor, House Committee on Public Health, P.O. Box 2910, Austin, Texas 78703, (512) 463–0806.
Filed: August 22, 1996, 3:42 p.m.

TRD-9612278

♦ ♦ ♦

Texas Department of Insurance

Monday, September 9, 1996, 9:00 a.m.

State Office of Administrative Hearings, 300 West 15th Street, Suite 502

Austin

AGENDA:

Prehearing Conference to consider whether disciplinary action should be taken against RICHARD LEWIS WALKER, Dallas, Texas, who holds a Group I, Legal Reserve Life Insurance Agent's License, a Local Recording Agent's License, a Managing General Agent's License, a Surplus Lines Agent's License and a Corporate Local Recording Agent's License issued by the Texas Department of Insurance.

Contact: Bernice Ross, 333 Guadalupe Street, Mail Code #113–2A, Austin, Texas 78701 (512) 463–6328.
Filed: August 23, 1996, 1:46 p.m.

TRD-9612352

♦ ♦ ♦

Monday, September 9, 1996, 1:00 p.m.

State Office of Administrative Hearings, 300 West 15th Street, Suite 502

Austin

AGENDA:

In the matter of IGNACIO INOCENCIO, JR.

Contact: Bernice Ross, 333 Guadalupe Street, Mail Code #113–2A, Austin, Texas 78701 (512) 463–6328.
Filed: August 23, 1996, 1:46 p.m.

TRD-9612353

♦ ♦ ♦

Tuesday, September 10, 1996, 9:00 a.m.

State Office of Administrative Hearings, 300 West 15th Street, Suite 502

Austin

AGENDA: 454–96–123C

To consider whether disciplinary action should be taken against JERRY WARREN BYARS, Graham, Texas, who holds a Group I, Legal Reserve Insurance Agent's Licence, a Variable Contract Agent's License, and a Local Recording Agent's License issued by the Texas Department of Insurance (cont. from 7–29–96).

Contact: Bernice Ross, 333 Guadalupe Street, Mail Code #113–2A, Austin, Texas 78701 (512) 463–6328.
Filed: August 23, 1996, 1:48 p.m.

TRD-9612355

♦ ♦ ♦

Tuesday, September 10, 1996, 9:00 a.m.

State Office of Administrative Hearings, 300 West 15th Street, Suite 502

Austin

AGENDA: 454–96–0876.11

In the Matter of PROFESSIONAL LIABILITY INSURANCE COMPANY, LTD., PHYSICIANS MALPRACTICE ANALYSTS AND DOROTHY FUQUA (cont. from 8–26–96)

Contact: Bernice Ross, 333 Guadalupe Street, Mail Code #113–2A, Austin, Texas 78701 (512) 463–6328.
Filed: August 23, 1996, 1:48 p.m.

TRD-9612354

♦ ♦ ♦

Wednesday, September 11, 1996, 1:00 p.m.

State Office of Administrative Hearings, 300 West 15th Street, Suite 502

Austin

AGENDA: 454–96–1469.C

To consider whether disciplinary action should be taken against TERRY D. TATE, Sulphur Springs, Texas, who holds a Group I, Legal Reserve Life Insurance Agent's License issued by the Texas Department of Insurance.

Contact: Bernice Ross, 333 Guadalupe Street, Mail Code #113–2A, Austin, Texas 78701 (512) 463–6328.
Filed: August 23, 1996, 1:48 p.m.

TRD-9612356

♦ ♦ ♦

Texas State Library

Wednesday, September 4, 1996, 10:00 a.m.

Texas State Library, Lorenzo Zavala Archives and Library, Room 314, 1201 Brazos Street

Austin

Texas Historical Records Advisory Board

AGENDA:

1. Call to Order
2. Approval of Minutes of Meeting — 05/10/96
3. Discussion of Final Revisions to Draft Strategic Plan
4. Discussion of NIIPRC Regrant Proposal
5. Report on Status of Revisions to Board Appointment Process
6. Public Comment
7. Determination of Site and Date of Next Meeting
8. Adjournment

Contact: Raymond Hill, Texas State Library, P.O. Box 12927, Austin, Texas 78711, (512) 463–5440
Filed: August 22, 1996, 9:29 a.m.

TRD-9612248

♦ ♦ ♦

Texas Department of Licensing and Regulation

Wednesday, September 4, 1996, 9:00 a.m.

920 Colorado, E.O. Thompson Building, 1st Floor, Room 108

Austin

Consumer Enforcement Division, Career Counseling

AGENDA:

According to the complete agenda, the Department will hold an Administrative Hearing to consider an award of damages to the complainant and assessment of administrative penalties against the Respondent, K.P. Allen & Associates (Dallas), for violations of the TEX.REV.CIV.STAT.ANN. art 5221a-8 (the Act) §§5(a), 7(b), 8(a) (two separate counts), and 8(c), pursuant to the Career Counseling Act, §12 and the TEX. GOVT. CODE ch.2001 (APA).

Contact: Paula Hamje, Hearings Examiner, 920 Colorado, E.O. Thompson Building, Austin, Texas 78701, (512) 463–3192.
Filed: August 23, 1996, 8:28 a.m.

TRD-9612302

♦ ♦ ♦

Thursday, September 5, 1996, 9:00 a.m.

920 Colorado, E.O. Thompson Building, 1st Floor, Room 108

Austin

Consumer Enforcement Division, Air Conditioning

AGENDA:

According to the complete agenda, the Department will hold an Administrative Hearing to consider the renewal of the air conditioning and refrigeration contractors license of Roy Swain Mitchell, Applicant, which is opposed by the Department based on previous violations of the TEX. CIV. STAT. ANN. art 8861 (the Act), pursuant to the Act §5 and art. 9100, 16 T.A.C. 75.25(b), and the TEX. GOVT. CODE, ch. 2001.

Contact: Paula Hamje, Hearings Examiner, 920 Colorado, E.O. Thompson Building, Austin, Texas 78701, (512) 463–3192.
Filed: August 23, 1996, 8:28 a.m.

TRD-9612303

♦ ♦ ♦

Texas Lottery Commission

Wednesday, August 28, 1996, 9:30 a.m.

6937 North IH35, American Founders Building, 1st Floor Auditorium

Austin

Emergency Revised Agenda:

AGENDA:

According to the agenda summary, the Texas Lottery Commission will call the meeting to order; approve minutes of the July 22, 1996 meeting; report by the Bingo Advisory Committee Chair and possible action on its activities; consideration and possible action on staff recommendations regarding bingo legislative issues; consideration and possible action on the activities of the House Licensing Committee on Bingo regarding charitable bingo; consideration and possible action on the Senate Interim Committee of Charitable Bingo's recommendations; consideration and possible action, including adoption, on proposed amendments on 16 TAC §401.368; consideration and possible action, including proposal of amendments, on 16 TAC §401.352; consideration and possible action, including proposed rulemaking, on the treatment of a prize in the event of a deceased prize winner; consideration and possible action on a proposed judicial order relating to prize winner Larry Williams; consideration and possible action on acquisition of a location for the Lottery headquarters, including renewal of the existing lease; including proposal of amendments, on 16 TAC §401.305; consideration and possible action, including proposal of amendments, on 16 TAC §401.308; consideration of the status and possible entry of an order in any contested case if a proposal for decision has been received from the assigned administrative law judge and the time period has lapsed for the filing of exceptions and replies; consideration and possible action on motions for rehearing; consideration and possible action on gambling issues; including devices and promotional cards; Commission may meet in Executive Session: return to open session for further deliberation and possible action on any matter discussed in Executive Session; Report by Executive Director and possible discussion on the operation of the agency, Commission planning calendar, financial status of the agency, HUB performance, and Legislative Appropriation-Request-Supplemental schedule letters; and Adjournment. For ADA assistance, call Michelle Guerrero at (512) 323–3791 at least two days prior to the meeting.

REASON FOR EMERGENCY: An Item was improperly noted for Executive session that should have been listed in the open portion of the meeting since it is a possible action item. The notice did not indicate that any item considered in executive session could have action taken in the open portion of the meeting.

Contact: Michelle Guerrero, 6937 North IH35, Austin, Texas 78752, (512) 323–3791.
Filed: August 21, 1996, 1:28 p.m.

TRD-9612214

♦ ♦ ♦

Texas State Board of Medical Examiners

Tuesday, August 27, 1996, 9:00 a.m.

333 Guadalupe, Tower 3, Suite 610

Austin

Hearings Division

Emergency Meeting

EMERGENCY REVISED AGENDA:

In addition to the previously posted agenda:

Probation Appearance, 10:00 a.m. — David M. McClellan, MD, Crosby, Texas

Termination Request, 2:00 p.m. — Louis A. Lopez, MD, Galveston, Texas

Termination Request, 2:30 p.m. — Mark D. Pucek, MD, Houston, Texas

Termination Request, 3:00 p.m. — Rafael Verduzco, MD, Sugarland, Texas

REASON FOR EMERGENCY: Information has come to the attention of the agency and requires prompt consideration.

Executive Session under authority of the Open Meetings Act, Section 551.071 of the Government Code and Article 4495b, Sections 2.07 (b) and 2.09.(o), Texas Revised Civil Statutes, regarding pending or contemplated litigation.

Contact: Pat Wood, P.O. Box 2018, Austin, Texas 78768–2018, (512) 305–7016.
Filed: August 22, 1996, 2:30 p.m.

TRD-9612267

♦ ♦ ♦

Texas Natural Resource Conservation Commission

Tuesday, August 27, 1996, 1:30 p.m.

12000 Park 35 Circle, IH35, Building E, Room 201–S

Austin

Water Well Drillers Advisory Council

EMERGENCY MEETING

AGENDA:

The Texas Water Well Drillers Advisory Council will meet with the Texas Natural Resource Conservation Staff to discuss the Water Well Driller and Pump Installer Certification Program.

REASON FOR EMERGENCY: This meeting was called by the Advisory Council Chairman to discuss the Water Well Driller/Pump Installer Certification Program.

Contact: Rick Wilder, P.O. Box 13087, M-C. 177, Austin, Texas 78711, (512) 239–0541.
Filed: August 21, 1996, 3:34 p.m.

TRD-9612233

♦ ♦ ♦

Thursday, August 29, 1996, 1:30 p.m.

12118 North IH35, Building E, Room 201–S

Austin

AGENDA:

This meeting is a work session for discussion between commissioners and staff. No public testimony or comment will be accepted except by invitation of the Commission or as set forth on individual items.

Contact: Doug Kitts, 12100 Park 35 Circle, Austin, Texas 78753, (512) 239–3317.
Filed: August 21, 1996, 2:33 p.m.

TRD-9612222

♦ ♦ ♦

Thursday, September 5, 1996, 3:00 p.m.

Natural Resources Center, Conference Room A, TAMU-CC, 6300 Ocean Drive

Corpus Christi

AGENDA:

I. Call to Order/Introductions/Minutes

II. Program Update

III. Preliminary Plan Section Reviews

IV. Other Business/Adjourn

Contact: Richard Volk, Program Director, Natural Resources Center, Suite 3300, 6300 Ocean Drive, Corpus Christi, Texas 78412, (512) 980–3420.
Filed: August 23, 1996, 9:11 a.m.

TRD-9612309

♦ ♦ ♦

Wednesday, September 11, 1996, 9:30 a.m.

12118 North IH35, Building E, Room 201–S

Austin

AGENDA:

The purpose of the hearing will be to determine whether a temporary order (TNRCC Docket. 96–1326–IWD) should be issued to GSE LINING TECHNOLOGY, INC. The Temporary Order, if issued, would authorize the discharge of treated domestic wastewater, reverse osmosis water treatment effluent and stormwater at a maximum volume not exceed 1,152,000 gallons during any 24–hour period. GSE Lining Technology Inc. operates a plastic forming company which is located on the south side of Richey Road and approximately 1 mile east of the intersection of Richey Road and the Hardy Toll Road in the City of Houston in Harris County, Texas. The applicant has stated that this request is justified to make necessary and unforeseen changes to its facility's discharge route.

Contact: Jim Bateman, Staff Attorney, P.O. Box 13087, Austin, Texas 78711–3087, (512) 239–0600.
Filed: August 22, 1996, 3:16 p.m.

TRD-9612272

♦ ♦ ♦

Wednesday, October 2, 1996, 10:00 a.m.

Administration Building, Commissioners Courtroom, Second Floor, 301 N. Thompson

Conroe

State Office of Administrative Hearings

AGENDA:

Notice of public hearing before an administrative law judge of the State Office of Administrative Hearings on an application by KARBROOKE, INC. for proposed Water Quality Permit No. 13810–01 to authorize the discharge of treated domestic wastewater effluent. The proposed wastewater treatment facility will be located on the south side of Marine Drive along the shoreline of Lake Conroe, approximately 750 feet east of the intersection of Diamond Drive and Marine Drive in Montgomery County, Texas.

Contact: Melissa Medina, State Office of Administrative Hearings, P.O. box 13025, Austin, Texas 78711, (512) 475–4993.
Filed: August 21, 1996, 10:02 a.m.

TRD-9612256

♦ ♦ ♦

Texas Natural Resource Conservation Commission

Tuesday, August 27, 1996, 1:30 p.m.

12000 Park 35 Circle, IH35, Building E, Room 201–S

Austin

Water Well Drillers Advisory Council

EMERGENCY MEETING

AGENDA:

The Texas Water Well Drillers Advisory Council will meet with the Texas Natural Resource Conservation Staff to discuss the Water Well Driller and Pump Installer Certification Program.

REASON FOR EMERGENCY: This meeting was called by the Advisory Council Chairman to discuss the Water Well Driller/Pump Installer Certification Program.

Contact: Rick Wilder, P.O. Box 13087, M-C. 177, Austin, Texas 78711, (512) 239–0541.
Filed: August 21, 1996, 3:34 p.m.

TRD-9612233

♦ ♦ ♦

Thursday, August 29, 1996, 1:30 p.m.

12118 North IH35, Building E, Room 201–S

Austin

AGENDA:

This meeting is a work session for discussion between commissioners and staff. No public testimony or comment will be accepted except by invitation of the Commission or as set forth on individual items.

Contact: Doug Kitts, 12100 Park 35 Circle, Austin, Texas 78753, (512) 239–3317.
Filed: August 21, 1996, 2:33 p.m.

TRD-9612222

♦ ♦ ♦

Thursday, September 5, 1996, 3:00 p.m.

Natural Resources Center, Conference Room A, TAMU-CC, 6300 Ocean Drive

Corpus Christi

AGENDA:

I. Call to Order/Introductions/Minutes

II. Program Update

III. Preliminary Plan Section Reviews

IV. Other Business/Adjourn

Contact: Richard Volk, Program Director, Natural Resources Center, Suite 3300, 6300 Ocean Drive, Corpus Christi, Texas 78412, (512) 980–3420.
Filed: August 23, 1996, 9:11 a.m.

TRD-9612309

♦ ♦ ♦

Wednesday, September 11, 1996, 9:30 a.m.

12118 North IH35, Building E, Room 201–S

Austin

AGENDA:

The purpose of the hearing will be to determine whether a temporary order (TNRCC Docket. 96–1326–IWD) should be issued to GSE LINING TECHNOLOGY, INC. The Temporary Order, if issued, would authorize the discharge of treated domestic wastewater, reverse osmosis water treatment effluent and stormwater at a maximum volume not exceed 1,152,000 gallons during any 24–hour period. GSE Lining Technology Inc. operates a plastic forming company which is located on the south side of Richey Road and approximately 1 mile east of the intersection of Richey Road and the Hardy Toll Road in the City of Houston in Harris County, Texas. The applicant has stated that this request is justified to make necessary and unforeseen changes to its facility's discharge route.

Contact: Jim Bateman, Staff Attorney, P.O. Box 13087, Austin, Texas 78711–3087, (512) 239–0600.
Filed: August 22, 1996, 3:16 p.m.

TRD-9612272

♦ ♦ ♦

Wednesday, October 2, 1996, 10:00 a.m.

Administration Building, Commissioners Courtroom, Second Floor, 301 N. Thompson

Conroe

State Office of Administrative Hearings

AGENDA:

Notice of public hearing before an administrative law judge of the State Office of Administrative Hearings on an application by KARBROOKE, INC. for proposed Water Quality Permit No. 13810–01 to authorize the discharge of treated domestic wastewater effluent. The proposed wastewater treatment facility will be located on the south side of Marine Drive along the shoreline of Lake Conroe, approximately 750 feet east of the intersection of Diamond Drive and Marine Drive in Montgomery County, Texas.

Contact: Melissa Medina, State Office of Administrative Hearings, P.O. box 13025, Austin, Texas 78711, (512) 475–4993.
Filed: August 21, 1996, 10:02 a.m.

TRD-9612256

♦ ♦ ♦

Texas Parks and Wildlife Department

Wednesday, August 28, 1996, 8:30 a.m.

Parks and Wildlife Headquarters, 4200 Smith School Road, Executive Office Conference Room

Austin

Public Lands Committee

AGENDA:

Approval of Committee Minutes of the previous meeting; Status Report on Committee Charges-Wildlife Management Area Access; CONSENT AGENDA- Nominations for Oil and Gas Leases — Fort Griffin State Historical Park-Shackelford County, Engeling Wildlife Management Area-Anderson County; ACTION- Proposed Public Lands Division Rules; BRIEFING-Proposed Sand, Shell, Gravel and Marl Regulations; BRIEFING-Sheldon Reservoir; Other Business.

Contact: Andrew Sansom, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, (512) 389–4642.
Filed: August 23, 1996, 9:13 a.m.

TRD-9612143

♦ ♦ ♦

Wednesday, August 28, 1996, 8:30 a.m.

Parks and Wildlife Headquarters, 4200 Smith School Road, Commission Hearing Room

Austin

Regulations Committee

AGENDA:

Approval of Committee Minutes of the previous meeting; CONSENT AGENDA- Sunset Adoptions— Broodfish Collection Repeal and New Rules, Possession and Sale of Deer Antler Rules, Alli-

gator Proclamation, Hunter Education Program Regulations, Easement Request Rules, Use of Uninscribed Vehicle Rules, CONSENT AGENDA- Sunset Proposals—Leasing of Farming or Grazing Rights; Sale of Products, Wildlife Management Association Area Hunting Lease License; Briefing-Scsooping Process; ACTION-Civil Restitution; ACTION– Taking, Possessing, and Transporting Threatened and Endangered Species- Sunset Provisions; ACTION- Wildlife Rehabilitation Regulations-Sunset Provisions; ACTION- Adoption of 1996–1997 Late Season Migratory Game Bird Season and Sunset Provisions; ACTION- Statewide Oyster Fishery Proclamation; ACTION-Statewide Shrimp Fishery Proclamation; Status of Regulations Committee Charges; Other Business

Contact: Andrew Sansom, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, (512) 389–4642.
Filed: August 23, 1996, 9:12 a.m.

TRD-9612144

♦ ♦ ♦

Wednesday, August 28, 1996, 8:30 a.m.

Parks and Wildlife Headquarters, 4200 Smith School Road, Commission Hearing Room

Austin

Finance Commission

AGENDA:

Approval of Committee Minutes of the previous meeting; Status Report of Finance Committee Charges, Briefing on Texas Outdoor Connection, Briefing on Per Person Pricing; ACTION- Combined FY97 Operating and Capital Budgets and FY98–99 Legislative Appropriations Request (LAR); Other business.

Contact: Andrew Sansom, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, (512) 389–4642.
Filed: August 23, 1996, 9:14 a.m.

TRD-9612145

♦ ♦ ♦

Wednesday, August 28, 1996, 2:00 p.m.

Parks and Wildlife Headquarters, 4200 Smith School Road, Commission Hearing Room

Austin

Parks and Wildlife Commission

AGENDA:

Presentation-TBBU; Presentation-DOW (after 3:00 p.m.); Annual Public Hearing concerning any issues relating to Parks and Wildlife.

Contact: Andrew Sansom, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, (512) 389–4642.
Filed: August 23, 1996, 9:15 a.m.

TRD-9612146

♦ ♦ ♦

Wednesday, August 28, 1996, 6:30 p.m.

Ruth's Chris Steakhouse, 3010 Guadalupe

Austin

Parks and Wildlife Commission

AGENDA:

Members of the Texas Parks and Wildlife Commission plan to have dinner at 6:30 p.m., August 28, 1996. Although this function is primarily a social event and no formal action is planned the Commission may discuss items on the Public Hearing Scheduled for 9:00 a.m., Thursday, August 29, 1996. (Agenda attached).

Contact: Andrew Sansom, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, (512) 389–4642.
Filed: August 23, 1996, 9:15 a.m.

TRD-9612147

♦ ♦ ♦

Thursday, August 29, 1996, 9:00 a.m.

Parks and Wildlife Headquarters, 4200 Smith School Road, Commission Hearing Room

Austin

Parks and Wildlife Commission

AGENDA:

Approval of the Commission Minutes from the previous meeting; Presentation of Retirement Certificates and Service Awards; Presentation of Association for Conservation Information Awards; Recognition-Matthew A. Thornberry; CONSENT AGENDA-Sunset Adoptions-Broodfish Collection Repeal and New Rules, Possession and Sale of Deer Antler Rules, Alligator Proclamation, Hunter Education Program Regulations, Easement Request Rules, Use of Uninscribed Vehicle Rules; CONSENT AGENDA-Nominations for Oil and Gas Leases—Fort Griffin State Historical Park-Shackelford County, Engeling Wildlife Management Area-Anderson County; ACTION-Local Indoor Recreation Projects; ACTION-Local Park Funding; ACTION-Boar Ramp Funding; ACTION-National Recreational Trails Grant Fund Awards; ACTION-Adoption of 1996–1997 Late Season Migratory Game Bird Season and Sunset Provisions; BRIEFING-Red River Chloride Project; ACTION-Combined FY97 Operating and Capital Budgets; ACTION-Civil Restitution; ACTION-Taking, Possessing and Transporting Threatened and Endangered Species-Sunset Provisions; ACTION-Wildlife Rehabilitation Regulations-Sunset Provisions; ACTION-Statewide Oyster Fishery Proclamation; ACTION Shrimp Fisher Proclamation.

Contact: Andrew Sansom, Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, (512) 389–4642.
Filed: August 23, 1996, 9:16 a.m.

TRD-9612148

♦ ♦ ♦

Structural Pest Control Board

Tuesday, September 3, 1996, 9:00 a.m.

Harris County Extension Center, 2 Abercrombie Drive

Houston

Public Hearing

AGENDA:

The Structural Pest Control Board will hold a public hearing on the following changes to the Structural Pest Control Board Law & Regulations.

I. Public Comment

II. 559.3 Treatment Standards

III. 559.4 Termite Treatment Disclosure

Contact: Benny Mathis, 9101 FM 1326, Suite 201, Austin, Texas 78758, (512) 835–4066.
Filed: August 21, 1996, 1:28 p.m.

TRD-9612213

♦ ♦ ♦

Friday, September 6, 1996, 9:00 a.m.

Harris County Extension Center, 2 Abercrombie Drive

Houston

Public Hearing

AGENDA:

The Structural Pest Control Board will hold a public hearing on the following changes to the Structural Pest Control Board Law & Regulations.

I. Public Comment

II. 559.3 Treatment Standards

III. 559.4 Termite Treatment Disclosure

Contact: Benny Mathis, 9101 FM 1326, Suite 201, Austin, Texas 78758, (512) 835–4066.
Filed: August 21, 1996, 1:28 p.m.

TRD-9612212

♦ ♦ ♦

Texas Department of Protective and Regulatory Services

Friday, September 6, 1996, 10:00 a.m.

Texas Law Center, 1414 Colorado at 15th Street, Room 104

Austin

Child Fatality Review State Committee Meeting

AGENDA:

Welcome. Committee Reports. Recommendations. Annual report. Discussion FY 96 and Goals for FY 97. Adjourn

Contact: Elaine Addison, P.O. Box 149030, Austin, Texas 78713–9030.
Filed: August 22, 1996, 12:35 p.m.

TRD-9612262

♦ ♦ ♦

Public Utility Commission of Texas

Tuesday, September 3, 1996, 9:00 a.m.

7800 Shoal Creek

Austin

Legal Administration

AGENDA:

A Prehearing conference has been scheduled for the above date and time in Docket No. 15923– PETITION OF COGEN LYONDELL, INC. FOR DECLARATORY ORDER ON ISSUES RELATING TO HOUSTON LIGHTING AND POWER COMPANY.

Contact: Paula Mueller, 7800 Shoal Creek Boulevard, Austin, Texas 78757, (512) 458–0100.
Filed: August 22, 1996, 9:29 a.m.

TRD-9612249

♦ ♦ ♦

Texas Council on Purchasing from People with Disabilities

Friday, September 6, 1996, 10:00 a.m.

Capitol Extension, Suite E 2.026, 1400 North Congress Avenue

Austin

Quarterly Council Meeting

AGENDA:

Approval of Minutes from June 14, 1996 Open Meeting;

Discussion and Action on New Services;

Discussion and Action on Renewal Services;

Discussion and Action on New Products;

Discussion and Action on Product Changes and Revisions;

Discussion of TIBH Industries, Inc. Management Fee;

Consideration of Repealed and Proposed Council Administrative Rules;

Discussion of Future Projects for Subcommittees

Presentation of TIBH Industries, Inc. Quarterly Activity Report;

Presentation by Texas Goodwill Industries;

Public Comment Period;

Suggested Agenda Items for Future Consideration;

Meeting Adjourn

Contact: Rose-Michel Munguia, 1711 San Jacinto, Austin, Texas 78701, (512) 463–6422
Filed: August 23, 1996, 8:29 a.m.

TRD-9612304

♦ ♦ ♦

Board of Tax Professional Examiners

Tuesday, September 3, 1996, 1:00 p.m.

Map Room, Dallas Central Appraisal District, 2949 North Stemmons Freeway

Dallas

AGENDA:

1. 1:00 Call to order

2. Determine the presence of a quorum

3. Recognition of Visitors

4. Discussion of Legislative Appropriation Request and Strategic Plan

5. Discussion of Complaints received by the board.

6. Discussion on Policy and Procedures changes. Sponsor requirements/RPA requirements/ Instructor requirements.

7. Adjourn

Contact: David Montoya, 333 Guadalupe Street, Tower 2, Suite 520, Austin, Texas 78701–3942, (512) 305–7300.
Filed: August 21, 1996, 2:33 p.m.

TRD-9612220

♦ ♦ ♦

Wednesday, September 4, 1996, 9:00 a.m.

Community room, Dallas Central Appraisal District, 2949 North Stemmons Freeway

Dallas

AGENDA:

1. 9:00 Call to order.

2. Determine the presence of a quorum.

3. Recognition of Visitors.

4. Approval of board minutes for May 1 and June 19, 1996, regular quarterly meetings.

5. Report from Professional Standards Committee. Linda Keylon, City of Plan.

6. Discussion and appropriate action on new Text for course 270.

7. Report on Education Program. Foy Mitchell, Dallas, C.A.D.

8. Discussion and appropriate action on complaint filed by Aspermont I.S.D.

9. Discussion and appropriate action on Policy and Procedure changes.

10. Discussion and appropriate action or vote on proposed rule changes.

11. Discussion of Strategic Plan and Legislative Appropriation Request (LAR).

12. Executive Director's report.

13. Discussion and appropriate action or vote on list of registrants who have met all requirements for Reclassification/Recertification since last regular quarterly meeting.

14. Determine date for next quarterly meeting.

15. Public comments on any relevant subject will be received without discussion.

16. Adjourn.

Contact: David Montoya, 333 Guadalupe Street, Tower 2, Suite 520, Austin, Texas 78701–3942, (512) 305–7300.

Filed: August 21, 1996, 2:33 p.m.

TRD-9612221

♦ ♦ ♦

Texas State Technical College System

Wednesday, August 28, 1996, 11:00 a.m.

LBJ Building, 111 East 17th Street, Room 212B

Austin

Board of Regents

AGENDA:

Selection of Financial Advisor Relative to Constitutional Bond Issue, Discuss Senate Education Committee Final Report, Consideration, Discussion and Possible Action Regarding Legislative Initiative in Light of the Senate Education Committee Report, and Discussion and Possible Action on General Legislative Strategy and Hierarchy of Command and Reporting on Said Strategy.

Contact: Sandra Krumnow, 3801 Campus Drive, Waco, Texas 76705, (817) 867–3964
Filed: August 23, 1996, 3:40 p.m.

TRD-9612391

♦ ♦ ♦

Wednesday, August 28, 1996, 11:15 a.m.

LBJ Building, 111 East 17th Street, Room 212B

Austin

Board of Regents Closed Meeting

AGENDA:

Closed meeting for the specific purpose provided in Sections 551.074 and 551.075. Section 551.074; Discussion on General Legislative Strategy Relative to Hierarchy of Command and Reporting on Said Strategy.

Contact: Sandra Krumnow, 3801 Campus Drive, Waco, Texas 76705, (817) 867–3964
Filed: August 23, 1996, 3:37 p.m.

TRD-9612389

♦ ♦ ♦

The Texas A&M University System

Monday, August 26, 1996, 9:15 a.m.

Board of Regents Meeting room, MSC Annex, Clark Street, Texas A&M University

College Station

Board of Regents

AGENDA:

The purpose of this special telephonic meeting is to consider any and all things leading to the appointment of the General Counsel of The Texas A&M University System; and if so desired, the Appointment of an individual to this position or any related action the board wishes to take regarding this position. Discussion regarding this subject will be held in closed session.

Contact: Vicki Running, The Texas A&M University System, College Station, Texas 77843, (409) 845–9600.
Filed: August 22, 1996, 9:29 a.m.

TRD-9612250

♦ ♦ ♦

Texas Department of Transportation

Wednesday, September 18, 1996, 1:30 p.m.

Texas Department of Transportation, 200 East Riverside, Building 200, Main Auditorium, Room 101

Austin

Interagency Abandoned Rail Corridor Committee

AGENDA:

Approval of Committee Minutes from April 30, 1996 meeting. Discussion of the future of Interagency Abandoned Rail Corridor Committee. Discussion of issues that may be affected by upcoming legislative session. Discussion of current status of forthcoming, pending, or recently authorized abandonments or sales.

Contact: Diane Northam, 125 East 11th Street, Austin, Texas 78701, (512) 463–8630.
Filed: August 26, 1996, 10:04 a.m.

TRD-9612458

♦ ♦ ♦

Tuesday, September 24, 1996, 1:00 p.m.

Texas Department of Transportation, 200 East Riverside, Building 150, Room 102

Austin

Tow Truck Rules Advisory Committee

AGENDA:

Introductions and Opening Remarks. Overview of Texas Transportation Commission Rules concerning advisory committees and the Open Meetings Act. Election of Committee Chairperson and Vice-Chairperson. In accordance with 43 TAC Section 1.84(b), Preliminary Review of Proposed Rulemaking Concerning Motor Carriers and Vehicle Storage Facilities.

Contact: Diane Northam, 125 East 11th Street, Austin, Texas 78701, (512) 463–8630.
Filed: August 26, 1996, 10:04 a.m.

TRD-9612457

♦ ♦ ♦

Texas Turnpike Authority

Wednesday, September 4, 1996, 10:00 a.m.

Conference Room, Administration Building, 3015 Raleigh Street

Dallas

Right-of-Way Acquisition Committee

AGENDA:

Roll Call of Committee Members.

Recognition of other Directors and Guests present.

1. Executive Session- pursuant to Chapter 551, Subchapter D, Texas Government Code; Sections 551.071, 551.072, and 551.073, deliberations concerning real property value, purchase, exchange, lease, negotiated settlement, and/or legal advisor fees included in Right-of-Way Appraisal/Offer/Purchase List No. 69, and advice from counsel concerning negotiations/settlement/offers related to the Dallas North Tollway, the President George Bush Turnpike, and/or The Addison Airport Toll Tunnel.

Consider approval and recommendation of Appraisal/Offer/Purchase List No. 69 for right-of-way parcels for the Addison Airport Toll Tunnel.

Discussion of Sunset Review of the TTA and other legislative proposals. No Action.

Adjournment.

Contact: Jimmie G. Newton, Secretary, 3015 Raleigh Street, Dallas, Texas 75219 (214) 522–6200.
Filed: August 23, 1996, 4:08 p.m.

TRD-9612408

♦ ♦ ♦

University Interscholastic League

Monday, August 26, 1996, 1:00 p.m.

Thompson Conference Center, 26th and Red River Streets

Austin

Waiver Review Board

EMERGENCY MEETING

AGENDA:

AA. Request for waiver of Parent Residence Rule by Jana Butler representing Glen Rose High School, in Glen Rose, Texas.

REASON FOR EMERGENCY: Appeal received in League office afternoon of August 22, 1996.

Contact: Sam Harper, 23001 Lake Austin Boulevard, Austin, Texas 78713, (512) 471–5883
Filed: August 22, 1996, 3:49 p.m.

TRD-9612279

♦ ♦ ♦

University of Texas at Austin

Monday, August 26, 1996, 10:00 a.m.

21st and San Jacinto Street, Alumni Center, Moffett Library

Austin

Council for Intercollegiate Athletics for Women

AGENDA:

I. Call to Order

II. Approval of the Minutes of Previous Meeting

III. New Business

IV. Announcements/Information Reports

V. Executive Session: Personnel Matters Relating to Appointment, Employment, Evaluation, Assignment, Duties, Discipline, or Dismissal of Officers or Employees — Section 551.074, the Texas Government Code.

VI. Adjournment

Contact: Jody Conradt, Director Women's Athletics, Bellmont Hall 718, Austin, Texas 78712–1286, (512) 471–7693.
Filed: August 23, 1996, 8:56 a.m.

TRD-9612306

♦ ♦ ♦

University of Texas, Health Center at Tyler

Thursday, September 5, 1996, 1:00 p.m.

Highway 271 and Highway 155, Room 113

Tyler

Animal Research Committee

AGENDA:

Approval of Minutes

Chairman Report

Animal Research Committee

Veterinarian Report

Old Business

Adjournment

Contact: Lea Alegre, ARC, UTHCT, P.O. Box 2003, Tyler, Texas 75710, (903) 877–7661.
Filed: August 22, 1996, 11:34 a.m.

TRD-9612259

♦ ♦ ♦
♦ ♦ ♦

The University of Texas System

Thursday, August 29, 1996, 9:00 a.m.

O. Henry Hall, 4th Floor, 601 Colorado Street

Austin

Board of Regents' Business Affairs and Audit Committee

AGENDA:

The Business Affairs and Audit Committee will convene in Open Session to recess immediately to Executive Session to confer with representatives of the Office of General Counsel and the Attorney General's Office regarding the LUNA vs U.T. SYSTEM litigation.

The Committee will reconvene in Open Session to formalize any actions resulting from the Executive Session Consideration.

Following the Open Session, the Committee will adjourn to a Briefing Session as permitted by law.

Contact: Arthur H. Dilly, 201 West Seventh Street, Austin, Texas 78701, 2981, (512) 499–4402.
Filed: August 23, 1996, 4:13 p.m.

TRD-9612413

♦ ♦ ♦

Thursday, August 29, 1996, 11:15 a.m.

Ninth Floor, Ashbel Smith Hall, 201 West 7th Street

Austin

Board of Regents

AGENDA:

The Board of Regents of the University of Texas will meet via telephone conference call to consider the ratification of Executive Committee Letters, 96–23 and 96–24 involving:

Amendments the Regents' Rules and Regulations relating to the delegation of contracting authority

Approval of a limited exception to the Regents' Rules and Regulations on solicitations to permit The University of Texas at Austin to consider corporate sponsorship arrangements for selected athletic contests.

Approval of a U.T. Austin Private Fund Development Campaign and renaming of Texas Memorial Stadium.

Contact: Arthur H. Dilly, 201 West Seventh Street, Austin, Texas 78701, 2981, (512) 499–4402.
Filed: August 23, 1996, 4:13 p.m.

TRD-9612412

♦ ♦ ♦

Texas Board of Veterinary Medical Examiners

Thursday, September 26, 1996, 1:00 p.m.

333 Guadalupe, Tower 2, Room 302, William P. Hobby Building

Austin

Examination Review Committee

AGENDA:

The Committee will meet to review the results of the September 26, 1996 State Board Examination for licensure.

Contact: Judy Smith, 333 Guadalupe, Suite 2–330, Austin, Texas 78701, (512) 305–7555.
Filed: August 22, 1996, 3:38 p.m.

TRD-9612275

♦ ♦ ♦

Regional Meetings

Meetings Filed August 21, 1996

Coastal Bend Workforce Development Board elected officials met at the Holiday Inn-Airport, 5549 Leopard Street, Corpus Christi, August 29, 1996 at 3:30 p.m. Information may be obtained from Deborah Seeger, 1616 Martin Luther King Drive, Corpus Christi, Texas 78401, (512) 889–5300. TRD 9612232.

Education Service Center, Region III Board of Directors, met at Victoria Regional Airport Road, Victoria, August 29, 1996 at 10:00 a.m. Information may be obtained from Julius D. Cano, 1905 Leary Lane, Victoria, Texas 77901, (512) 573–0731. TRD 9612217.

Education Service Center, Region III Board of Directors met at 1905 Leary Lane, Victoria, August 29, 1996 at 1:30 p.m. Information may be obtained from Julius D. Cano, 1905 Leary Lane, Victoria, Texas 77901, (512) 573–0731. TRD 9612218.

Education Service Center, Region 10 Board of Directors, met at 400 East Spring Valley Road, Richardson, August 28, 1996 at 1:15 p.m. Information may be obtained from Joe Farmer, ESC 10, 400 East Spring Valley Road, Richardson, Texas 75081, (214) 231–6301, extension 302. TRD 9612231.

Ellis County Appraisal District, Appraisal Review Board met at 400 Ferris Avenue, Waxahachie, August 26, 1996 at 9:00 a.m. Information may be obtained from Dorothy Phillips, P.O. Box 878, Waxahachie, Texas 75165, (214) 937–3552. TRD 9612224.

Golden Crescent Private Industry Council met at 2401 Houston Highway, Victoria, August 28, 1996 at 6:30 p.m. Information may be obtained from Sandy Hiermann, 2401 Houston Highway, Victoria, Texas 77901, (512) 576–5872. TRD 9612215.

Lee County Appraisal District Board of Directors met at 218 East Richmond Street, Giddings, on August 28, 1996 at 9:00 a.m. Information may be obtained from Roy Holcomb, 218 East Richmond Street, Giddings, Texas 78942, (409) 542–9618. TRD 9612194.

Lubbock Regional MHMR Center, Board of Trustees met at 1602 10th Street, Board Room, Lubbock, august 26, 1996 at 12:00 p.m. Information may be obtained from Gene Menefee, P.O. Box 2828, Lubbock, Texas 79408, (806) 766–0202. TRD 9612228.

Lubbock Regional MHMR Center, Board of Trustees Program Committee, met at 1602 10th Street, Board Room, Lubbock, August 26, 1996 at 10:00 a.m. Information may be obtained from Gene Menefee, P.O. Box 2828, 1602 10th Street, Lubbock, Texas 79408, (806) 766–0202. TRD 9612229.

Lubbock Regional MHMR Center, Board of Trustees Resource Committee, met at 1602 10th Street, Conference Room, Lubbock August 26, 1996 at 11:00 a.m. Information may be obtained from Gene Menefee, P.O. Box 2828, 1602 10th Street, Lubbock, Texas 79408, (806) 766–0202. TRD 9612230.

Trinity River Authority of Texas, Board of Directors, met at 5300 South Collins Street, Arlington, August 28, 1996 at 10:00 a.m. Information may be obtained from James L. Murphy, Trinity River Authority of Texas, P.O. Box 60, Arlington, Texas 76004, (817) 467–4343. TRD 9612216.

Upper Leon River Municipal Water District Board of Directors, EMERGENCY MEETING, met at the General Office, Located off FM 2861, Lake Proctor Dam, Comanche, August 22, 1996 at 6:30 p.m. Information may be obtained from Gary Lacy, Upper Leon River Municipal Water District, P.O. Box 67, Comanche, Texas 76442, (817) 879–2258. TRD 9612237.

Meetings Filed August 22, 1996

Central Plains Center for MHMR and SA, Board of Trustees met at 208 South Columbia, Plainview, August 29, 1996 at 6:00 p.m. Information may be obtained from Ron Trusler, 2700 Yonkers, Plainview, Texas 79072, (806) 293–2636. TRD 9612266.

Central Texas Opportunities, Inc., Board of Directors met at 1200 South Frio Street, Coleman, August 27, 1996 at 7:00 p.m. Information may be obtained from Barbara Metcalf, P.O. Box 820, Coleman, Texas 78634, (915) 625–4167. TRD 9612253.

Concho Valley Council of Governments, Private Industry Council, met at 5014 Knickerbocker Road, San Angelo, August 28, 1996 at 3:00 p.m. Information may be obtained from Monette Molinar, 5002 Knickerbocker Road, San Angelo, Texas 76906, (915) 944–9666, TRD 9612274.

Panhandle Ground Water Conservation District 3, Board of Directors Public Meeting, met at District Office, 300 South Omohundro Street, White Deer, August 28, 1996 at 4:00 p.m. Information may be obtained from C.E.Williams, Box 637, White Deer, Texas, 79097, (806) 883–2501. TRD 9612263.

Panhandle Ground Water Conservation District 3, Board of Directors Public Meeting, met at District Office, 300 South Omohundro Street, White Deer, August 28, 1996 at 7:30 p.m. Information may be obtained from C.E.Williams, Box 637, White Deer, Texas 79097, (806) 883–2501. TRD 9612264.

Panhandle Regional Planning Commission, Board of Directors met at 415 West 8th Avenue, Amarillo, August 29, 1996 at 1:30 p.m. Information may be obtained from Rebecca Rusk, P.O. Box 9257, Amarillo, Texas 79105, (806) 372–3381. TRD 9612251.

San Antonio-Bexar County Metropolitan Planning Organization, Transportation Steering Committee, met at the International Conference Center, Convention Center Complex, San Antonio, on August 26, 1996 at 1:30 p.m. Information may be obtained from Charlotte A. Roszelle, 604 Navarro, Suite 904, San Antonio, Texas 78205, (210) 227–8651. TRD 9612257.

San Jacinto River Authority, Board of Directors met at 2301 North Millbend Drive, Woodlands, August 18, 1996 at 12:30 p.m. Information may be obtained from James R. Adams or Ruby Shiver, P.O. Box 329, Conroe, Texas 77305, (409) 588–1111. TRD 9612269.

South Plains Regional Workforce Development Board met at 1625 13th Street, Lubbock, August 27, 1996 at 3:00 p.m. Information may be obtained from Linda Chamales, P.O. Box 2000, Lubbock, Texas 79457. TRD 9612258.

Southwest Milam Water Supply Corporation Board met at 114 East Cameron, Rockdale, August 26, 1996 at 7:00 p.m. Information may be obtained from Dwayne Jekel, P.O. Box 232, Rockdale, Texas 76567, (512) 446–2604. TRD 9612273.

Tarrant Appraisal District, Appraisal Review Board, will meet at 2329 Gravel Road, Fort Worth, September 9, 10, 11, 12, 16, 18, 19, 23, 24, 25, and 26, 1996, at 8:00 a.m. Information may be obtained from Linda Smith, 2329 Gravel Road, Fort Worth, Texas 76118–6984, (817) 284–8884. TRD 9612265.

Texas Panhandle Mental Health Authority, Board of Trustees, TPMHA, met at 7201 IH40 West, 2nd floor, Amarillo on August 29, 1996 at 9:00 a.m. Information may be obtained from Shirley Hollis, P.O. Box 3250, Amarillo, Texas 79116–3250, (806) 353–3699. TRD 9612271.

Texas Panhandle Mental Health Authority, Board of Trustees, TPMHA, met at 7201 IH40 West, 2nd floor, Amarillo on August 29, 1996 at 10:30 a.m. Information may be obtained from Shirley Hollis, P.O. Box 3250, Amarillo, Texas 79116–3250, (806) 353–3699. TRD 9612270.

Texas Water Conservation Association Risk Management Fund, Board of Trustees Meeting, met at JI Speciality Services, Inc. 9420 Research Boulevard, Echelon III, Suite 120, Austin, August 29, 1996

at 2:00 p.m. . Information may be obtained from Leroy Goodson, 221 East 9th Street, Suite 206, Austin, Texas 78701, (512) 472–7216. TRD 9612255.

Meetings Filed August 23, 1996

Alamo Area Council of Governments, 911 Area Judges Committee, met at 118 Broadway, Suite 400, San Antonio on August 28, 1996, at 10:00 a.m. Information may be obtained from Al J. Notzon, AACOG, 118 Broadway, Suite 400, San Antonio, Texas 78205, (210) 225–5201. TRD 9612312.

Alamo Area Council of Governments , Board of Directors, met at 118 Broadway, Suite 400, San Antonio on August 28, 1996, at 1:00 p.m. Information may be obtained from Al J. Notzon, AACOG, 118 Broadway, Suite 400, San Antonio, Texas 78205, (210) 225–5201. TRD 9612314.

Alamo Area Council of Governments, Rural Area Judges, met at 118 Broadway, Suite 400, San Antonio, August 28, 1996, at 11:30 a.m. Information may be obtained from Al J. Notzon, AACOG, 118 Broadway, Suite 400, San Antonio, Texas 78205, (210) 225–5201. TRD 9612313.

Ark-Tex Council of Governments (ATCOG), Executive Committee, met at the Franklin County Courthouse, District Courtroom, Mt. Vernon, August 29, 1996 at 5:30 p.m. Information may be obtained from Sandie Brown, P.O. Box 5307, Texarkana, Texas 75505. TRD 9612301.

Atascosa County Appraisal District, Appraisal Review Board, met at 4th and Avenue J, Poteet, August 29, 1996, at 9:00 a.m. Information may be obtained from Curtis Stewart, P.O. Box 139, Poteet, Texas 78065, (210) 742–3591. TRD 9612308.

Austin-Travis County MHMR Center, Finance and Control Committee, met at 1430 Collier Street, Board Room, Austin, August 27, 1996, at 12:00 noon. Information may be obtained from Sharon Taylor, 1430 Collier Street, Austin, Texas 78704, (512) 440–4031. TRD 9612334.

Bandera County Appraisal District, Appraisal Review Board, met at 1116 Main Street, Bandera, August 28, 1996 at 9:00 a.m. Information may be obtained from P.H. Coates, P.O. Box 1119, Bandera, Texas 78003, (210) 796–3039. TRD 9612378.

Carson County Appraisal District, Board of Directors met at 102 Main Street, Panhandle, August 28, 1996, at 9:00 a.m. Information may be obtained from Donita Herber, Boc 970, Panhandle, Texas 79068, (806) 537–3569. TRD. 9612381.

Carson County Appraisal District, Board of Directors met at 102 Main Street, Panhandle, August 28, 1996, at 9:15 a.m. Information may be obtained from Donita Herber, Boc 970, Panhandle, Texas 79068, (806) 537–3569. TRD. 9612382.

Dallas Area Rapid Transit Audit Committee met at 1401 Pacific, Dallas, Conference Room "B", August 27, 1996, at 1:00 p.m. Information may be obtained from Paula J. Bailey, DART, P.O. Box 660163, Dallas, Texas 75266–0163. TRD 9612347.

Dallas Area Rapid Transit Committe of the Whole met at 1401 Pacific, Dallas, Conference Room "C", First Floor, August 27, 1996, at 11:00 a.m. Information may be obtained from Paula J. Bailey, DART, P.O. Box 660163, Dallas, Texas 75266–0163. TRD 9612348.

Dallas Area Rapid Transit Board met at 1401 Pacific, Dallas, August 27, 1996, at 6:30 p.m. Information may be obtained from Paula J. Bailey, DART, P.O. Box 660163, Dallas, Texas 75266–0163. TRD 9612349.

Education Service Center, Region XI, Board of Directors, met at 3001 North Freeway, Fort Worth, August 27, 1996, at 10:00. Information may be obtained from Dr. Ray Chancellor, Director, ESC XI, 3001 North Freeway, Fort Worth, Texas 761006, (817) 625–5311. TRD 9612307.

Edwards Aquifer Authority Ad-Hoc Critical Period Management Committee met at 1615 North St. Marys Street, San Antonio, August 28, 1996 at 4:00 p.m. Information may be obtained from Sally Tamez-Salas, 1615 North St. Mary's Street, San Antonio, Texas 78212, (210) 222–2204. TRD 9612351.

Edwards Aquifer Authority Finance Committee met at 1615 North St. Marys Street, San Antonio, on August 28, 1996 at 6:00 p.m. Information may be obtained from Sally Tamez-Salas, 1615 North St. Mary's Street, San Antonio, Texas 78212 (210) 222–2204. TRD 9612358.

Edwards Aquifer Authority Litigation Oversight Committee met at 1615 North St. Marys Street, San Antonio, on August 29, 1996 at 4:30 p.m. Information may be obtained from Sally Tamez-Salas, 1615 North St. Mary's Street, San Antonio, Texas 78212 (210) 222–2204. TRD 9612357.

Heart of Texas Region, MHMR Center, Board of Trustees met at 110 South 12th Street, Waco, August 27, 1996, 11:45 a.m. Information may be obtained from Helen Jasso, P.O. Box 76703, (817) 752–3451, Extension 290. TRD 9612383.

Hickory Underground Water Conservation District No. 1, Board and Advisors, met at 2005 South Bridge, Brady, August 28, 1996 at 5:00 p.m. Information may be obtained from Stan Reinhard, P.O. Box 1214, Brady, Texas 76825, (915) 597–2785. TRD 9612305.

Permian Basin Regional Planning Commission, Board of Directors, Permian Basin Private Industry Council met at 2910 La Force Boulevard, Midland, August 28, 1996 at 10:00 a.m. Information may be obtained from Carole B. Symonette, P.O. Box 60660, Midland, Texas 79711-0660 (915) 563–1061. TRD 9612297.

Middle Rio Grande Development Council, Executive Committee, met at the Holiday Inn, 920 East Main Street, Uvalde, August 27, 1996 at 6:30 p.m. Information may be obtained from Leodoro Martinez, MRGDC, P.O. Box 1199, Carrizo Springs, Texas 78834, (210) 876–3533. TRD 9612362.

Middle Rio Grande Development Council, Board of Directors, met at the Holiday Inn, 920 East Main Street, Uvalde, August 27, 1996 at 8:00 p.m. Information may be obtained from Leodoro Martinez, MRGDC, P.O. Box 1199, Carrizo Springs, Texas 78834, (210) 876–3533. TRD 9612363.

Middle Rio Grande Development Council, Board of Directors met at the Holiday Inn, 920 East Main, Uvalde, August 28, 1996 at 1:00 p.m. Information may be obtained from Leodoro Martinez, MRGDC, P.O. Box 1199, Carrizo Springs, Texas 78834, (210) 876–3533. TRD 9612364.

Sharon Water Supply Corporation Board of Directors met at the office of Sharon Water Supply Corporation, Route 5, Box 50361, Winnsboro, August 26, 1996, 7:00 p.m. Information may be obtained

from Gerald Brewer, Route 5, Box 50361, Winnsboro, Texas 75494, (903) 342–3525. TRD 9612335.

South Texas Private Industry Council, Inc. met at Highway 83, Zapata, August 29, 1996, 4:00 p.m. Information may be obtained from Mrs. Myrna V. Herbst, P.O. Box 1757, Laredo, Texas 78044–1757, (210) 722–0546. TRD 9612300.

South Texas Workforce Development Board met at Highway 83, Zapata, August 29, 1996, 4:30 p.m. Information may be obtained from Mrs. Myrna V. Herbst, P.O. Box 1757, Laredo, Texas 78044–1757, (210) 722–0546. TRD 9612299.

Texas Municipal Power Agency ("TMPA"), Board of Directors Special Meeting, met at Holiday Inn Select, LBJ Northeast, Elm Room, 11350 LBJ Freeway at South Jupiter, August 26, 1996, at 3:00 p.m. Information may be obtained from Carl Shahady, P.O. Box 7000; Bryan, Texas 77805, (409) 873–2013. TRD 9612311.

Meetings Filed August 26, 1996

Riceland Regional Mental Health Authority, Finance/HR Committee will meet at 4910 Airport, Rosenberg, August 30, 1996 at 2:00 p.m. Information may be obtained from Marjorie Dornak, P.O. Box 869, Wharton, Texas 77488, (409) 532–3098. TRD 9612469.

IN ADDITION

The ***Texas Register*** is required by statute to publish certain documents, including applications to purchase control of state banks, notices of rate ceilings, changes in interest rate and applications to install remote service units, and consultant proposal requests and awards.

To aid agencies in communicating information quickly and effectively, other information of general interest to the public is published as space allows.

Texas Commission on Alcohol and Drug Abuse

Correction of Error

The Texas Commission on Alcohol and Drug Abuse adopted an amendment to §148.61. The rule appeared in the July 30, 1996, issue of the *Texas Register* (21 TexReg 7267).

Under the definition of Qualified Credentialed Counselor (QCC), the last sentence should read as follows: The following professionals are eligible to serve as qualified credentialed counselors:

(A)-(D) (No changes.)

(E) licensed physician;

(F)-(H) (No changes.)

♦ ♦ ♦

Texas Alternative Fuels Council

Notices of Request for Proposals

The Texas Alternative Fuels Council (AFC) was created by the Texas Legislature (S. B. 737, Acts of 73rd Legislature, Regular Session, 1993) to coordinate a comprehensive statewide program to support the use of environmentally beneficial alternative fuels in vehicle fleets. The AFC is authorized to finance programs and activities supporting or encouraging the use of alternative fuels.

Pursuant to authority granted in Texas Natural Resource Code, Chapter 113, Subchapter J, the AFC hereby requests proposals for engineering services to assist with the development and implementation of an alternative fueled vehicle program that will result in the optimization and United State Environmental Protection Agency (EPA) Clean Fuel Vehicle certification of vehicle fueling systems using the FTP75 testing procedure. The certifications must include systems that are fueled by propane and result in at least the low emission vehicle (LEV) standard, with ultra low emission vehicle (ULEV) and inherently low emission vehicle (ILEV) standards preferred. The contract period is expected to begin upon AFC approval and end August 31, 1997.

The requested engineering services will require specific experience in the optimization and EPA FTP75 certification of vehicle fueling systems. The engineer should have received documentation from an EPA recognized emissions testing facility showing the ability to consistently obtain at least LEV standards through the FTP75 testing procedures, with ULEV and ILEV documentation preferred.

Closing Date: Proposals must be received in the Texas Alternative Fuels Council office no later than 5:00 p.m. Central Zone Time (CZT), on September 12, 1996. An application is considered filed when actually received in the Council office or when postmarked showing the application was received and accepted by the United States Postal Service, a common carrier or its equivalent, at least four calendar days prior to submission date. Metered mail is not acceptable unless it also includes a United States Postal Service postmark. Proposals received after this time will not be considered.

Award procedure: Proposals will be subject to evaluation by the AFC Executive Committee based on the evaluation criteria set forth in the Request for Proposal (RFP). The AFC Executive Committee will determine which proposal best meets these criteria and then make a recommendation to the AFC. The AFC will make the final decision. A proposer may be asked to clarify his proposal, which may include an oral presentation prior to the final selection.

The Texas Alternative Fuels Council reserves the right to accept or reject any or all proposals submitted. The AFC is under no legal or other obligation to execute a contract on the basis of this notice or the distribution of any RFP. Neither this notice nor the RFP commits the Texas Alternative Fuels Council to pay for any costs incurred prior to the execution of a contract.

The anticipated schedule of events is as follows: Issuance of RFP is Friday, August 30, 1996, 1:00 p.m. CZT; proposals are due September 12, 1996, 5:00 p.m. CZT; and contract execution will be upon approval by the AFC or as soon thereafter as possible.

Contact: Parties interested in submitting a proposal should contact R. Craig Davis, Administrator, Texas Alternative Fuels Council, P.O. Box 13047, Austin, Texas 78711-3047 (mail) or 1700 North Congress Avenue, Room 124, Austin, Texas 78701, to obtain a copy of the RFP. The RFP will be available for pick-up at the referenced address

on Friday, August 30 between 1:00 p.m. and 5:00 p.m. CZT and thereafter, during normal business hours.

Issued in Austin, Texas, on August 26, 1996

TRD-9612472
Carol Milner
Texas Register Liaison
Texas Alternative Fuels Council
Filed: August 26, 1996

♦ ♦ ♦

The Texas Alternative Fuels Council (AFC) was created by the Texas Legislature (S. B. 737, Acts of 73rd Legislature, Regular Session, 1993) to coordinate a comprehensive statewide program to support the use of environmentally beneficial alternative fuels in vehicle fleets. The AFC is authorized to finance programs and activities supporting or encouraging the use of alternative fuels.

Pursuant to authority granted in Texas Natural Resource Code, Chapter 113, Subchapter J, the AFC hereby requests proposals for consulting services to assist with: (1) the development and implementation of alternative fueled vehicle strategic plans for Texas Clean Cities efforts and (2) the development and implementation of a private loan fund program to be used by both public and private sector vehicle fleets in lieu of the existing Texas Alternative Fuels Council loan program. The consulting period is expected to begin after AFC approval and the successful negotiation of a contract and end August 31, 1997.

Closing Date: Proposals must be received in the Texas Alternative Fuels Council office no later than 5:00 p.m. Central Zone Time (CZT), on September 30, 1996. An application is considered filed when actually received in the AFC offices or when postmarked showing the application was received and accepted by the United States Postal Service, a common carrier or its equivalent, at least four calendar days prior to submission date. Metered mail is not acceptable unless it also includes a United States Postal Service postmark. Proposals received after this time will not be considered.

Award procedure: Proposals will be subject to evaluation by the AFC Executive Committee based on the evaluation criteria set forth in the Request for Proposal (RFP). The AFC Executive Committee will determine which proposal best meets these criteria and then make a recommendation to the AFC. The AFC will make the final decision. A proposer may be asked to clarify his proposal, which may include an oral presentation prior to the final selection.

The Texas Alternative Fuels Council reserves the right to accept or reject any or all proposals submitted. The AFC is under no legal or other obligation to execute a contract on the basis of this notice or the distribution of any RFP. Neither this notice nor the RFP commits the Texas Alternative Fuels Council to pay for any costs incurred prior to the execution of a contract.

The anticipated schedule of events is as follows: Issuance of RFP is Friday, August 30, 1996, 1:00 p.m. CZT; proposals are due September 30, 1996, 5:00 p.m. CZT; and contract execution will be upon approval by the AFC or as soon thereafter as possible.

Contact: Parties interested in submitting a proposal should contact R. Craig Davis, Administrator, Texas Alternative Fuels Council, P.O. Box 13047, Austin, Texas 78711-3047 (mail) or 1700 North Congress Avenue, Room 124, Austin, Texas 78701, to obtain a copy of the RFP. The RFP will be available for pick-up at the referenced address on Friday, August 30 between 1:00 p.m. and 5:00 p.m. CZT and thereafter, during normal business hours.

Issued in Austin, Texas, on August 26, 1996

TRD-9612470
Carol Milner
Texas Register Liaison
Texas Alternative Fuels Council
Filed: August 26, 1996

♦ ♦ ♦

The Texas Alternative Fuels Council (AFC) was created by the Texas Legislature (S. B. 737, Acts of 73rd Legislature, Regular Session, 1993) to coordinate a comprehensive statewide program to support the use of environmentally beneficial alternative fuels in vehicle fleets. The AFC is authorized to finance programs and activities supporting or encouraging the use of alternative fuels.

Pursuant to authority granted in Texas Natural Resource Code, Chapter 113, Subchapter J, the AFC hereby requests proposals for projects that initiate or expand the use of propane as an alternative vehicular fuel. Proposals are requested: (1) to perform after market conversions of late model, high mileage fleet vehicles to operate on propane, (2) to cover the incremental cost of purchasing Original Equipment Manufacturer (hereinafter OEM) alternative fuel fleet vehicles (AFVs) capable of operating on propane, or (3) to demonstrate heavy duty dedicated propane OEM engine technology for mass transit applications that can be certified, at a minimum, to the United States Environmental Protection Agency Low Emission Vehicle (LEV) standards. Proposals for propane fleet conversions must be matched with not less than 50% of the total conversion or incremental cost by the applicant. Proposals for heavy duty engine demonstrations must be matched at not less than 50% of total cost and may include in kind services as part of the match.

Up to $200,000 is available to fund projects selected under this RFP. It is anticipated that individual projects would be funded up to a maximum of $100,000.

All proposals must be received in the Texas Alternative Fuels Council office no later than 5:00 p.m. Central Zone Time (CZT), on Tuesday, September 30, 1996. An application is considered filed when actually received in the AFC offices or when postmarked showing the application was received and accepted by the United States Postal Service, a common carrier or its equivalent, at least four calendar days prior to submission date. Metered mail is not acceptable unless it also includes a United States Postal Service postmark. Proposals received after this time will not be considered.

Any contract resulting from this Request for Proposals shall contain provisions prescribed by the AFC prohibiting discrimination in employment.

Parties interested in submitting a proposal should contact R. Craig Davis, Administrator, Texas Alternative Fuels Council, P.O. Box 13047, Austin, Texas 78711-3047 (mail) or 1700 North Congress Avenue, Room 124, Austin, Texas 78701, to obtain a copy of the RFP.

Issued in Austin, Texas, on August 26, 1996

TRD-9612471
Carol Milner
Texas Register Liaison

Texas Alternative Fuels Council
Filed: August 26, 1996

♦ ♦ ♦

Comptroller of Public Accounts

Notice of Consultant Contract Amendment

In accordance with the provisions of Chapter 2254, Subchapter B of the Texas Government Code, the Comptroller of Public Accounts, on behalf of the Texas Prepaid Higher Education Tuition Board, announces this notice of consultant contract amendment.

The award of the original consultant contract was published in the August 29, 1995, issue of the *Texas Register* (20 TexReg 6763).

The amendment provides that the consultant will assist the Comptroller in proposing contract prices for four prepaid tuition college plans, as identified by the Comptroller, that are to be offered to the general public by the board for the enrollment period of November 18, 1996, through February 17, 1997.

The consulting services sought by the Comptroller relate to services previously provided by Ernst and Young L.L.P., 600 Peachtree Street, Suite 2800, Atlanta, Georgia 30308. The Comptroller intends to amend Ernest and Young's contract unless a better offer is received. Parties interested in submitting an offer should contact the Comptroller of Public Accounts, Senior Legal Counsel's Office, 111 East 17th Street, Room 113, Austin, Texas 78774, (512) 475-0866. Offers must be received no later than September 15, 1996.

The dollar value of the amendment is expected to be approximately $10,000.00 to 15,000.00 and total value of the amended consultant contract is expected not to exceed $109,186.00–114,186.00.

Issued in Austin, Texas, on August 26, 1996.

TRD–9612446
Arthur F. Lorton
Senior Legal Counsel
Comptroller of Public Accounts
Filed: August 26, 1996

♦ ♦ ♦

Office of the Consumer Credit Commissioner

Notice of Rate Ceiling

The Consumer Credit Commissioner of Texas has ascertained the following rate ceilings by use of the formulas and methods described in Title 79, Texas Civil Statutes, Article 1.04, as amended (Texas Civil Statutes, Article 5069-1.04).

Issued in Austin, Texas, on August 20, 1996.

TRD-9612252
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissoner
Filed: August 22, 1996

♦ ♦ ♦

Texas Department of Health

Request for Proposal/ Pilot Project to Provide Primary Care Health Insurance for Children Enrolled at Farias Elementary School in Laredo, Texas

The Texas Department of Health and City of Laredo Health Department have developed a request for proposal for a pilot project to provide primary care health insurance for children enrolled at Farias Elementary School in Laredo, Texas.

The purpose of the pilot project is to provide primary care health insurance for eligible children enrolled at Farias Elementary and to determine the feasibility of administering such a program on a statewide basis, identify marketing and enrollment issues associated with such a plan, and to determine cost and utilization data for plan enrollees.

The project start date is November 1, 1995 and will run through October 31, 1997. The request for proposal will be available on September 1, 1996 and may be obtained by contacting: Mr. Jerry

Robinson, Director, Laredo Health Department, 2600 Cedar Street, Laredo, Texas 78040, (210) 723-2051.

The Texas Department of Health and the Laredo Health Department reserve the right to reject any or all applications and are not liable for any costs incurred by the applicant in the development, submission, or review of the application. Any costs incurred in the preparation of the application shall be borne by the applicant and are not allowable in this request for proposal.

Issued in Austin, Texas, on August 26, 1996.

TRD-9612429
Linda Kotek
General Counsel
Texas Department of Health
Filed: August 26, 1996

♦ ♦ ♦

Department of Information Resources

Invitation to Negotiate, Phase I — TDCJ Reengineering Project

The Department of Information Resources (DIR) on behalf of the Texas Department of Criminal Justice (TDCJ) requests all interested parties to submit a proposal for consulting services to assist DIR and TDCJ with TDCJ's offender information management reengineering project.

DIR is assisting TDCJ with this project by providing project and contract management expertise and assistance in obtaining the right consulting firm for this effort. The consulting services needed at this time are for Phase I of this three phase project.

Phase I consists of identifying both internal and external stakeholders, mapping all of the agency's process and information classes, visioning the future environment, gaining an understanding of how the existing environment does or does not support that vision, and then based upon all the previous input, identifying reengineering target areas. This information along with a baseline assessment of where the agency currently is will provide an overall picture from which the reengineering consultant will assist the agency project team with prioritizing the target reengineering areas. The resulting prioritized list will show the interdependencies of each area and will allow the agency to understand the overall impact of specific change. The consultant in Phase I will also be required to provide an estimate for Phase II activities.

Interested parties can obtain a copy of the detailed Invitation to Negotiate by contacting the DIR Technology Information Center at (512) 475-4790 or by downloading it from DIR's home page on the world wide web. Address: www.dir.state.tx.us/busops/its/tdcjitn.

Notice of Intent to respond is requested to be received by DIR by 5:00 p.m.(C.S.T.) September 10, 1996. Proposals must be received no later than 5:00 p.m.(C.S.T.), September 17, 1996, at the following address: Cynthia P. Long, Department of Information Resources, 300 West 15th Street, Suite 1300, Austin, Texas 78711.

All proposals must be sealed and clearly marked "TDCJ Offender Information Management Reengineering Project". All cost information must be submitted in a separately bound document. Questions relating to this Invitation to Negotiate should be addressed to Ron Weiss, Project Manager, at the previous listed address or faxed to (512) 475-4759.

Proposals will be reviewed by the Texas Department of Information Resources in conjunction with the Texas Department of Criminal Justice. A selection team will meet with the top qualified consultants whose proposals meet the project outcome requirements. Factors serving as the basis of selection will include the firm's and project team members' qualifications, expertise and past experience in reengineering projects, as well as expertise in the area of information technology. A contractor will be selected only from among those approved for negotiation, and must be a qualified information systems vendor with an approved catalogue on file with the General Services Commission in accordance with the catalogue purchase procedure. The determination of the most qualified consultant shall be at the sole discretion of the Department of Information Resources.

Issued in Austin, Texas, on August 21, 1996.

TRD–9612204
C.J. Brandt
General Counsel
Department of Information Resources
Filed: August 21, 1996

♦ ♦ ♦

Texas Department of Insurance

Correction of Error

The Texas Department of Insurance proposed new §5.3700. The rule appeared in the August 6, 1996, issue of the *Texas Register* (21 TexReg 7337).

Under Tables and Graphics. The following error was submitted:

78741 Kelly AFB Bexar 1...

It should read: 7841 San Antonio Bexar 1...

♦ ♦ ♦

Texas Department of Insurance

Insurer Services

The following applications have been filed with the Texas Department of Insurance and are under consideration:

Application for admission in Texas for The Koa Fire and Marine Insurance Company, Ltd. (U.S. Branch), a foreign fire and casualty company. The home office is in New York, New York.

Application for admission in Texas for Health Care Service Corporation, a Mutual Legal Reserve Company, a foreign mutual accident and health company. The home office is in Chicago, Illinois.

Application for a name change in Texas for Pioneer Life Insurance Company of Illinois, a foreign life, accident and health company. The proposed new name is Pioneer Life Insurance Company. The home office is in Schaumburg, Illinois.

Application for a name change in Texas for Northwestern National Life Insurance Company, a foreign life, accident and health company. The proposed new name is Reliastar Life Insurance Company. The home office is in Minneapolis, Minnesota.

Any objections must be filed within 20 days after this notice was filed with the Texas Department of Insurance, addressed to the attention of Cindy Thurman, 333 Guadalupe Street, M/C 305-2C, Austin, Texas 78701.

Issued in Austin, Texas, on August 26, 1996.

TRD-9612451
Caroline Scott
General Counsel and Chief Clerk
Texas Department of Insurance
Filed: August 26, 1996

♦ ♦ ♦

Legislative Budget Board and Governor's Office of Budget and Planning

REVISION to the Schedule for Joint Budget Hearings (for the period September 2-6, 1996) on Appropriations Requests for the 1998-99 biennium, as published in the August 27, 1996, issue of the *Texas Register*

The budget hearing scheduled for the Teacher Retirement System and Optional Retirement Program (September 4, 9:00 a.m) has been RESCHEDULED for September 10, 1996, at 9:00 a.m., Room 106, John H. Reagan Building, 105 West 15th Street, Austin, Texas.

Issued in Austin, Texas, on August 22, 1996.

TRD-9612291
Judith S. King
Analyst
Legislative Budget Board
Filed: August 22, 1996

♦ ♦ ♦

Texas Natural Resource Conservation Commission

Extension of Deadline for Written Comments

The Texas Natural Resource Conservation Commission (TNRCC) has extended its deadline to receive written comments for the proposed repeal of existing Chapter 285 and a proposed new Chapter 285, relating to on-site sewage facilities.

The proposal was published in the July 16, 1996, issue of the *Texas Register*. The deadline for receipt of written comments to the proposed changes was originally published as 30 days after the date of publication, but has been extended to September 3, 1996.

For further information contact Michael Fahy, Field Operations Division, P.O. Box 13087, Austin, Texas 78711-3087, (512) 239-1490.

Issued in Austin, Texas, on August 21, 1996.

TRD–9612205
Kevin McCalla
Director, Legal Division
Texas Natural Resource Conservation Commission
Filed: August 21, 1996

♦ ♦ ♦

Notice of Application to Appropriate Public Waters of the State of Texas

The following notices of application for permits to appropriate Public Waters of the State of Texas were issued during the period of August 7, 1996 and August 21, 1996.

SABINE RIVER AUTHORITY OF TEXAS; application for extension of time to commence and complete modifications of proposed hydroelectric facilities pursuant to §11.145, Texas Water Code, and Texas Natural Resource Conservation Commission Rules 30 TAC §295.1, et seq. Certificate of Adjudication Number 05-4658, as amended, includes authorization for Sabine River Authority to construct hydroelectric facilities in the spillway of Toledo Bend Reservoir on the Sabine River, Sabine River Basin, in Newton County, Texas. On September 25, 1990 the Commission issued an order indicating that construction of these facilities was to commence by June 5, 1996 and be completed by June 5, 1997. Applicant is requesting an extension on the commencement date for construction to October 1, 1998, and the completion date to October 1, 2000. Applicant stated they are requesting this time extension because they are optimistic that laws will be passed in Texas' next legislative session (beginning in January 1997) that will allow the Authority to provide water for hydroelectric power to potential customers.

CITY OF KELLER; Application Number 5553 for a permit pursuant to §11.121, Texas Water Code, and TNRCC Rules 30 TAC §295.1, et seq to construct and maintain a reservoir on an unnamed tributary of Big Bear Creek, tributary of West Fork Trinity River, tributary of the Trinity River, Trinity River Basin, and impound therein not to exceed 5.15 acre-feet of water for recreation purposes. The impoundment would be located in the City of Keller, approximately 1700 feet southwest of the intersection of Highway 377 and FM 1709 in Tarrant County, Texas.

TEXAS PARKS AND WILDLIFE DEPARTMENT; Application Number 5555 for a permit pursuant to §11.121, Texas Water Code, and TNRCC Rules 30 TAC §295.1, et seq for authority to construct a wetland development site through the retention of overflows of Morral Bayou, Alazan Bayou, and the Angelina River in the Neches River Basin. Morral Bayou is a tributary of Alazan Bayou which is a tributary of Bayou Loco which is a tributary of the Angelina River which is a tributary of the Neches River. The levee system will consist of approximately 11,560 feet of one to four foot high levees and roadways and will create an off-channel reservoir complex with a surface area of 112 acres, and impound therein a maximum of 168 acre-feet of water. The project will be located approximately 10.0 miles south of Nacogdoches in Nacogdoches County, Texas.

CITY OF LUBBOCK; Application Number 12-3705A to amend Certificate of Adjudication Number 12-3705 pursuant to §11.122, Texas Water Code, and TNRCC Rules 30 TAC §295.1, et seq. Certificate of Adjudication 12-3705 currently authorizes owner to maintain 3 existing dams and reservoirs, to enlarge an existing dam and reservoir, construct 2 dams and reservoirs, all located within the Brazos River Basin in Lubbock County, Texas. Owner is authorized to use all of the aforesaid reservoirs for in-place recreational purposes with no right of diversion. The City of Lubbock seeks to amend the Certificate Number 12-3705 for authorization to divert water from 3 of the reservoirs to irrigate land known as the Berl Huffman Athletic Complex, Buddy Holly Park, and 98.13 acres of land which includes 54.95 acres known as Mae Simmons Park, all within the vicinity of

the respective reservoirs. All land to be irrigated is owned by the City of Lubbock.

The Executive Director may approve these applications unless a written hearing request is filed in the Chief Clerk's Office of the TNRCC within 30 days after newspaper publication of the notice of application. To request a hearing, you must submit the following: (1) your name (or for a group or association, an official representative), mailing address, daytime phone number, and fax number, if any; (2) the name of the applicant and the application number; (3) the statement "I/we request a public hearing;" (4) a brief description of how you would be adversely affected by the granting of the application in a way not common to the general public; and (5) the location of your property relative to the applicant's operations.

If a hearing request is filed, the Executive Director will not approve the application and will forward the application and hearing request to the TNRCC Commissioners for their consideration at a scheduled Commission meeting. If a hearing is held, it will be a legal proceeding similar to civil trials in state district court.

If you wish to appeal a permit issued by the Executive Director, you may do so by filing a written Motion for Reconsideration with the Chief Clerk of the Commission no later than 20 days after the date the Executive Director signs the permit.

Requests for a public hearing or questions concerning procedures must be submitted in writing to the Chief Clerk's Office, MC 105, TNRCC, P.O. Box 13087, Austin, Texas 78711-3087, (512) 239-3315.

Issued in Austin, Texas, on August 23, 1996.

TRD-9612360
Gloria A. Vasquez
Chief Clerk
Texas Natural Resource Conservation Commission
Filed: August 23, 1996

♦ ♦ ♦

Notice of Applications for Waste Disposal Permits

Attached are Notices of Applications for waste disposal permits issued during the period of August 15th thru August 23, 1996.

The Executive Director will issue these permits unless one or more persons file written protests and/or a request for a hearing within 30 days after newspaper publication of this notice.

If you wish to request a public hearing, you must submit your request in writing. You must state (1) your name, mailing address and daytime phone number; (2) the permit number or other recognizable reference to this application; (3) the statement "I/we request a public hearing;" (4) a brief description of how you, or the persons you represent, would be adversely affected by the granting of the application; (5) a description of the location of your property relative to the applicant's operations; and (6) your proposed adjustment to the application/permit which would satisfy your concerns and cause you to withdraw your request for hearing. If one or more protests and/or requests for hearing are filed, the Executive Director will not issue the permit and will forward the application to the Office of Hearings Examiners where a hearing may be held. In the event a hearing is held, the Office of Hearings Examiners will submit a recommendation to the Commission for final decision. If no protests or requests for hearing are filed, the Executive Director will sign the permit 30 days after newspaper publication of this notice or thereafter. If you wish to appeal a permit issued by the Executive Director, you may do so by filing a written Motion for Reconsideration with the Chief Clerk of the Commission no later than 20 days after the date the Executive Director signs the permit.

Information concerning any aspect of these applications may be obtained by contacting the Texas Natural Resource Conservation Commission, Chief Clerks Office-MC105, P.O. Box 13087, Austin, Texas 78711, (512) 239-3300.

Listed are the name of the applicant and the city in which the facility is located, type of facility, location of the facility, permit number and type of application-new permit, amendment, or renewal.

AIR PRODUCTS INCORPORATED, P.O. Box 3326, Pasadena, Texas 77501-3326, a facility that manufactures organic and inorganic chemicals, the plant site is at 1423 State Highway 225, northeast of Red Bluff Road in the City of Pasadena in Harris County, Texas, renewal, 02382.

ADJUTANT GENERAL'S DEPARTMENT, P.O. Box 5218, Austin, Texas 78763-5218, the wastewater treatment facilities are approximately 1/2 mile southeast of the intersection of U.S. Highway 271 and Farm-to-Market Road 2648 in Lamar County, Texas, renewal, 13249-01.

CLAUDE NORMAN AND DIAN NORMAN, 214 Watts Lane, Canyon Lake, Texas 78133, the wastewater treatment facilities are on King Arthur Court in the northeast corner of Sommersetshire Estates, approximately 2,000 feet southeast of the intersection of County Road 93 and Hughes Ranch Road in Brazoria County, Texas, renewal, 12978-01.

BOB CROUCH, Route 3 Box 3, Dublin, Texas 76446, the dairy is at the northwest corner of the intersection of Farm-to-Market Roads 219 and 2156, approximately two miles northwest of Dublin in Erath County, Texas, amendment, 03216.

BRENDA DAMRON, 5000 CR300, Zephyr, Texas 76890, the dairy is approximately five miles southeast of Blanket, Brown County, Texas, on County Road 300. From Blanket, head south on Farm-to-Market Road 1467 approximately 4 miles, then turn east onto County Road 300 and follow the road through a right turn and the dairy will be located on the east side of the road in Brown County, Texas, new, 03910.

FINE ORGANICS CORPORATION, 6655 West Bay Road, Baytown, Texas 77520, a petroleum refinery and organic chemical manufacturing plant, the plant site is at 6655 West Bay Road, adjacent and east of Cedar Bayou, approximately 2.5 stream miles south of the State Highway 146 Cedar Bayou Bridge and northeast of the City of Baytown in Chambers County, Texas, renewal, 02777.

FLINTLOCK, LTD., 6937 Flintlock, Houston, Texas 77040, an establishment involved in the manufacturing and distribution of decorative candles, the plant site is located 1,400 feet north of the intersection of West Little York Road and Fairbanks North Houston Road in Harris County, Texas, new, 13848-01.

THE GOODYEAR TIRE & RUBBER COMPANY, 11570 North U.S. Highway 277, San Angelo, Texas 76905, a tire evaluation facility, the plant site is on the east side of South Highway 277, approximately seven miles northeast of the intersection of U.S. Highway 67 and U.S. Highway 277, northeast of the City of San Angelo in Tom Green County, Texas, amendment, 03750.

HARDIN COUNTY WATER CONTROL AND IMPROVEMENT DISTRICT NUMBER 1, 101 Pinegarden Lane, Sour Lake, Texas 77659, the wastewater treatment plant is north of Little Pine Island Bayou, approximately two miles north of the intersection of State Highway 105 and Pine Wood Boulevard in Hardin County, Texas, renewal, 10678-01.

CITY OF JOURDANTON, 1220 Simmons Avenue, Jourdanton, Texas 78026, the wastewater treatment facilities are approximately 0.5 mile southwest of the intersection of State Highways 16 and 97 and approximately one mile west of the intersection of State Highway 16 and Farm-to-Market Road 1332 in Atascosa County, Texas, renewal, 10418-01.

LAJITAS UTILITY COMPANY, INC., in care of Southern Investors Services Company, Inc., 2727 North Loop West, Suite 200, Houston, Texas 77008, the wastewater treatment facilities are approximately 900 feet south of Ranch-to-Market Road 170 and 2,200 feet east of Rio Grande in Brewster County, Texas, amendment, 12167-01.

CITY OF MERIDIAN, P.O. Box 205, Meridian, Texas 76665, the Meridian Plant Number 2 Wastewater Treatment Facilities are located at 501 South Main Street approximately 2,900 feet east-northeast of the intersection of State Highway 6 and State Highway 22 in Bosque County, Texas, amendment, 10113-02.

OWENS CORNING FIBERGLASS CORPORATION, 3700 North IH 35 East, Waxahachie, Texas 75165, a fiberglass wool insulation products manufacturing plant, the plant site is located adjacent to Interstate Highway 35, approximately four miles north of the City of Waxahachie, Ellis County, Texas, renewal, 01178.

CITY OF PORT NECHES, P.O. Box 758, Port Neches, Texas 77651, the water treatment plant is located approximately 1.25 miles northwest of the intersection of Farm-to-Market Road 366 and State Highway Loop 136 in Jefferson County, Texas, renewal, 10477-01.

QUEST SEPARATION TECHNOLOGIES, INC., 12500 Bay Area Boulevard, Pasadena, Texas 77507, a polyethylene wax refining and tolling facility, The plant site is at 12500 Bay Area Boulevard in the City of Pasadena in Harris County, Texas, amendment, 03686.

CITY OF SAN MARCOS, 630 East Hopkins Street, San Marcos, Texas 78666, the City of San Marcos Wastewater Plant Number 2 is on the north bank of the San Marcos River, approximately 4,000 feet east of the intersection of State Highway 123 and Interstate Highway 35 in the City of San Marcos in Hays County, Texas, 10273-002.

CITY OF STOCKDALE, P.O. Box 446, Stockdale, Texas 78160, the wastewater treatment facilities are on the southeast side of County Road 401 (Old Floresville Road), approximately 1,500 feet southwest of the intersection of U.S. Highway 87 and County Road 401 in Wilson County, Texas, renewal, 10292-01.

TEXAS MUNICIPAL POWER AGENCY, P.O. Box 7000, Bryan, Texas 77805, Gibbons Creek Lignite Mine, the mine site is located along both sides of State Highway 30, 0.75 miles west of the intersection of State Highway 30 and Farm-to-Market Road 244, near the City of Carlos, Grimes County, Texas, renewal, 02460.

TEXAS PARKS & WILDLIFE DEPARTMENT AND ATHENS MUNICIPAL WATER AUTHORITY, 4200 Smith School Road, Austin, Texas 78744, Texas Freshwater Fishery Center; the plant site is adjacent to Farm-to-Market Road 2495, approximately one mile south of the intersection of Farm-to-Market Road 2495 and Farm-to-Market Road 317, near the City of Athens in Henderson County, Texas, new, 03897.

TEXAS PARKS AND WILDLIFE DEPARTMENT, 4200 Smith School Road, Austin, Texas 78744, the wastewater treatment facilities are in Purtis Creek State Park, approximately 0.4 mile west of the intersection of Farm-to-Market Road 316 and Goshen Road in Henderson County, Texas, renewal, 12190-01.

WELLBORN RESOURCES LLC, P.O. Box 6733, Bryan, Texas 77805, the Wellborn Resources LLC Wastewater Treatment Facilities are 4,500 feet southwest of Farm-to- Market Road 2154 on Koppe Bridge Road and approximately one mile south of Wellborn in Brazos County, Texas, new, 13850-01.

Issued in Austin, Texas, on August 23, 1996.

TRD-9612361
Gloria A. Vasquez
Chief Clerk
Texas Natural Resource Conservation Commission
Filed: August 23, 1996

♦ ♦ ♦

Notice of Delisting of State Superfund Site

The Executive Director of the Texas Natural Resource Conservation Commission (TNRCC) by this notice is issuing a final public notice of delisting a facility from the State Registry (State Superfund List) of sites which may constitute an imminent and substantial endangerment to public health and safety or the environment due to a release or threatened release of hazardous substances into the environment.

The delisted site is the PIP Minerals State Superfund Site which was originally placed on the State Superfund Registry list on January 22, 1988 (13 TexReg 427-428). The 2.29-acre site is located at 3303 « Beaumont Avenue in Liberty, Texas. The site is north of Old Beaumont Road and east of the Route 146 Bypass in Liberty County, Texas. Located on the northeastern part of the site is a warehouse with floor dimensions of 80 feet by 100 feet. The warehouse is a metal shell on a concrete slab.

The site was used for a drilling-mud mixing operation and a storage facility for drilling mud additives and drilling chemicals from 1982 until 1985. Six tanks containing diesel fuel and drilling fluids and approximately 60 drums containing sodium bichromate and other materials were left at the site. The site also contained two areas where sodium bichromate and other wastes were allegedly buried. Trenching activities done in 1988 revealed that there were no buried wastes on site, and all drums and tanks were removed from the site by 1991.

An Investigative Study and Baseline Risk Assessment were completed in February, 1996 on the PIP Minerals site. The results documented some soluble/hexavalent chromium at several locations on the property. Concentrations of barium above background were also noted in several site soils and ditch-bottom sediments.

The Investigative Study report, which was approved by TNRCC on February 29, 1996, concluded that under the most conservative future land use (residential use), the existing levels of chromium and/or barium do not pose a threat to human health or the environment. A qualitative evaluation of the potential for adverse effects to crops

and animals concluded that no adverse impacts are predicted under conservative current and future land use projections.

This notice is issued to finalize the delisting process which began on March 5, 1996 when a potentially responsible party (PRP), pursuant to 30 TAC §335.344(a), submitted a letter to the executive director requesting the executive director to delete (delist) the PIP Minerals site from the State Registry based on the findings and conclusions presented in these above referenced approved reports which demonstrate that the site does not pose an imminent and substantial endangerment to public health and safety or the environment and that no further remedial action is appropriate. TNRCC has determined this property can be safely used for residential development without any further remediation.

A notice of TNRCC's intent to delist the site was published in the Texas Register (21 TexReg 5637-5638) on June 18, the Liberty Vindicator on June 16, 1996, and the Liberty Gazette on June 19, 1996. In these published notices it was stated that "pursuant to 30 TAC §335.344(b) The Commission shall hold a public contested case hearing ... on requests filed pursuant to subsection (a) of this section, provided that a written request for hearing is filed with the chief hearings examiner of the Commission by any PRP... or any interested person, within 30 days after receipt of a determination by the executive director made pursuant to a request filed in accordance with subsection (a) of this section. The TRNCC did not receive any requests for a hearing from any interested persons during the request period. Therefore, the PIP Minerals State Superfund site is hereby delisted.

All inquiries regarding the delisting of the Pip Minerals site should be directed to Rob Conti, TNRCC Project Manager, at 1-800-633-9363.

Issued in Austin, Texas on August 23, 1996.

TRD-9612345
Kevin McCalla
Director, Legal Division
Texas Natural Resource Conservation Commission
Filed: August 23, 1996

♦ ♦ ♦

Provisionally-Issued Temporary Permits to Appropriate State Water

Listed below are permits issued during the period of August 23, 1996

Application Number TA-7711 by Texaco Pipeline, Inc. for diversion of 1 acre-foot in a 3-month period for industrial purposes. Water may be diverted from the Highway 273 crossing of the North Fork Red River, approximately 19 miles southeast of Pampa, Gray County, Texas, Red River Basin. The Executive Director of the TNRCC has reviewed each application for the permits listed and determined that sufficient water is available at the proposed point of diversion to satisfy the requirements of the application as well as all existing water rights. Any person or persons who own water rights or who are lawful users of water on a stream affected by the temporary permits listed above and who believe that the diversion of water under the temporary permit will impair their rights may file a complaint with the TNRCC. The complaint can be filed at any point after the application has been filed with the TNRCC and the time the permit expires. The Executive Director shall make an immediate investigation to determine whether there is a reasonable basis for such a complaint. If a preliminary investigation determines that diversion under the temporary permit will cause injury to the complainant the commission shall notify the holder that the permit shall be cancelled without notice and hearing. No further diversions may be made pending a full hearing as provided in §295.174. Complaints should be addressed to Water Rights Permitting Section, Texas Natural Resource Conservation Commission, P.O. Box 13087, Austin, Texas 78711, Telephone (512) 239-4433. Information concerning these applications may be obtained by contacting the Texas Natural Resource Conservation Commission, P.O. Box 13087, Austin, Texas 787311, (512) 239-3300.

Issued in Austin, Texas, on August 23, 1996.

TRD-9612359
Gloria A. Vasquez
Chief Clerk
Texas Natural Resource Conservation Commission
Filed: August 23, 1996

♦ ♦ ♦

Texas Department of Protective and Regulatory Services

Notice of Intent to Contract-Screening at Intake

Under the provisions of the Texas Government Code, Chapter 2254, Subchapter B, the Texas Department of Protective and Regulatory Services (PRS) is proposing to contract for services necessary to continue to develop and implement a federally funded project entitled "Innovations in Child Protective Services: Screening At Intake". These services will build on a child welfare statistical modeling process developed by the American Human Association. Unless a better offer to provide these services is received, PRS will issue the award of this purchase of services to the American Humane Association (AHA) aka/dba American Association for Protecting Children.

DESCRIPTION OF SERVICES: Consultation to continue developing and implementing a methodology for using a statistical modeling process to help identify cases at intake which can safely be screened out and not investigated and cases which can be screened in for an abbreviated investigation and assessment process and for more efficient delivery of services to prevent serious injury or death cases. A retrospective study, a prospective study and comparison analyses will be conducted to determine implementation feasibility.

ELIGIBLE APPLICANTS: Eligible applicants are Historically underutilized Businesses, public or private profit or nonprofit agencies, and individuals with demonstrated knowledge, competence, and qualifications in developing and implementing similar methodology that can be used in coordination with a PRS specified child welfare statistical modeling process.

CLOSING DATE FOR RECEIPT OF OFFERS, MODIFICATION OF OFFERS, OTHER REQUESTS: The last date that offers and modifications of offers and other requests will be received is Wednesday, September 18, 1996, at 4:00 p.m. PRS shall be the sole and final arbitrator of when offers are received based on post mark prior to the closing date or log of hand delivery of offers before or on the closing date.

NECESSARY CREDENTIALS: PRS program management staff will assess any new offers and determine if potential consultants have (1) provided ample service description, (2) demonstrated

relevant prior experience, including proven ability to build upon and coordinate with a specified child welfare statistical modeling process, and (3) made an offer of reasonable consultant fees. These credentials are necessary for the project.

AMOUNT OF AWARD AND LIMITATIONS: The amount of the award for these services shall not exceed $20,000.00. Funding will be dependent upon available federal appropriations, under the block grant "Innovations in Child Protective Services". PRS reserves the absolute right to reject any and all offers received in response to this notice of intent to purchase services, and to amend, suspend, or cancel this notice in whole or in part if it is deemed in PRS's best interest.

CONTACT PERSON: Requests for further information pertaining to this purchase of services may be addressed in writing only to the attention of the Texas Department of Protective and Regulatory Services, Deborah Williams, PSFC Purchased Services, 701 W. 51st St., P. O. Box 149030, Austin, Texas 78714-9030 (78751). Official replies will be in writing from designated PRS personnel.

Issued in Austin, Texas on August 23, 1996.

TRD-9612310
C. Ed Davis
Deputy Commissioner for Legal Services
Texas Department of Protective and Regulatory Services
Filed: August 23, 1996

♦ ♦ ♦

Public Utility Commission of Texas

Notices of Intent to File Pursuant to Substantive Rule §23.27

Notice is given to the public of the intent to file with the Public Utility Commission of Texas an application pursuant to Public Utility Commission Substantive Rule 23.27 for approval of customer-specific PLEXAR-Custom Service for Region VI in Houston, Texas.

Tariff Title and Number. Application of Southwestern Bell Telephone Company for PLEXAR-Custom Service for Region VI in Houston, Texas. Pursuant to Public Utility Commission Substantive Rule 23.27. Tariff Control Number 16322.

The Application. Southwestern Bell Telephone Company is requesting approval for an Optional Features addition to the existing PLEXAR-Custom service for Region VI. The geographic service market for this specific service is the Houston, Texas area.

Persons who wish to comment upon the action sought should contact the Public tility Commission of Texas, at 7800 Shoal Creek Boulevard, Austin, Texas 78757, or call the Public Utility Commission Consumer Affairs Division at (512) 458-0256, or (512) 458-0221 for teletypewriter for the deaf.

Issued in Austin, Texas, on August 2, 1996.

TRD-9612366
Paula Mueller
Secretary of the Commission
Public Utility Commission of Texas
Filed: August 23, 1996

♦ ♦ ♦

Notice is given to the public of the intent to file with the Public Utility Commission of Texas an application pursuant to Public Utility Commission Substantive Rule 23.27 for approval of customer-specific PLEXAR-Custom Service for Camino Real Bank, N.A. in San Antonio, Texas, formerly known as Texas Bank, San Antonio, Texas.

Tariff Title and Number. Application of Southwestern Bell Telephone Company for PLEXAR-Custom Service for Camino Real Bank, N.A. in San Antonio, Texas, formerly known as Texas Bank, San Antonio, Texas. Pursuant to Public Utility Commission Substantive Rule 23.27. Tariff Control Number 16292.

The Application. Southwestern Bell Telephone Company is requesting approval for a 14 station addition to the existing PLEXAR-Custom service for Camino Real Bank, N.A. in San Antonio, Texas, formerly known as Texas Bank, San Antonio, Texas. The geographic service market for this specific service is the San Antonio, Texas area.

Persons who wish to comment upon the action sought should contact the Public Utility Commission of Texas, at 7800 Shoal Creek Boulevard, Austin, Texas 78757, or call the Public Utility Commission Consumer Affairs Division at (512) 458-0256, or (512) 458-0221 for teletypewriter for the deaf.

Issued in Austin, Texas, on August 21, 1996.

TRD–9612226
Paula Mueller
Secretary of the Commission
Public Utility Commission of Texas
Filed: August 21, 1996

♦ ♦ ♦

Notice is given to the public of the intent to file with the Public Utility Commission of Texas an application pursuant to Public Utility Commission Substantive Rule 23.27 for approval of customer-specific PLEXAR-Custom Service for NationsBanc Services, Inc. in Austin, Texas.

Tariff Title and Number. Application of Southwestern Bell Telephone Company for PLEXAR-Custom Service for NationsBanc Services, Inc. in Austin, Texas. Pursuant to Public Utility Commission Substantive Rule 23.27. Tariff Control Number 16326.

The Application. Southwestern Bell Telephone Company is requesting approval for a 100 station addition to the existing PLEXAR-Custom service for NationsBanc Services, Inc. The geographic service market for this specific service is the Austin, Texas area.

Persons who wish to comment upon the action sought should contact the Public Utility Commission of Texas, at 7800 Shoal Creek Boulevard, Austin, Texas 78757, or call the Public Utility Commission Consumer Affairs Division at (512) 458-0256, or (512) 458-0221 for teletypewriter for the deaf.

Issued in Austin, Texas, on August 2, 1996.

TRD-9612368
Paula Mueller
Secretary of the Commission
Public Utility Commission of Texas
Filed: August 23, 1996

♦ ♦ ♦

Notice is given to the public of the intent to file with the Public Utility Commission of Texas an application pursuant to Public Utility Commission Substantive Rule 23.27 for approval of customer-specific PLEXAR-Custom Service for Region VI Education Service Center in Houston, Texas.

Tariff Title and Number. Application of Southwestern Bell Telephone Company for PLEXAR-Custom Service for Region VI Education Service Center in Houston, Texas. Pursuant to Public Utility Commission Substantive Rule 23.27. Tariff Control Number 16323.

The Application. Southwestern Bell Telephone Company is requesting approval for a new PLEXAR-Custom service for Region VI Education Service Center. The geographic service market for this specific service is the Houston, Texas area.

Persons who wish to comment upon the action sought should contact the Public tility Commission of Texas, at 7800 Shoal Creek Boulevard, Austin, Texas 78757, or call the Public Utility Commission Consumer Affairs Division at (512) 458-0256, or (512) 458-0221 for teletypewriter for the deaf.

Issued in Austin, Texas, on August 2, 1996.

TRD-9612367
Paula Mueller
Secretary of the Commission
Public Utility Commission of Texas
Filed: August 23, 1996

♦ ♦ ♦

Texas Department Transportation

Requests for Proposals

Notice of Invitation: The Texas Department of Transportation (TxDOT) intends to engage engineers, pursuant to Texas Government Code, Chapter 2254, Subchapter A, and 43 TAC §§9.30-9.40, to provide the following services. Selected engineering firms must perform a minimum of 30% of the actual contract work to qualify for contract award.

Contract Number 02-645P5004 and 02-645P5005: Each off-System bridge contract will require services for public involvement including environmental assessment, complete roadway and bridge design, scour analysis, plan development, specifications assemblage, construction cost estimate, right-of-way map preparation. The locations of these projects are as follows: Erath County, East Collins Street at North Bosque River; Johnson County, CR 600 at Walnut Creek, CR 600 Tributary at Walnut Creek, and CR 1118 at Brazos River; Parker County, CR 2045 (Maddux Road) over Dry Creek and Underwood at Clear Fork Trinity River; and Tarrant County, Keller-Haslet Road at Buffalo Creek. Contract Number 02-645P5004 and 02-645P5005: Each off-System bridge contract will require services for public involvement including environmental assessment, complete roadway and bridge design, scour analysis, plan development, specifications assemblage, construction cost estimate, right-of-way map preparation. The locations of these projects are as follows: Erath County, East Collins Street at North Bosque River; Johnson County, CR 600 at Walnut Creek, CR 600 Tributary at Walnut Creek, and CR 1118 at Brazos River; Parker County, CR 2045 (Maddux Road) over Dry Creek and Underwood at Clear Fork Trinity River; and Tarrant County, Keller-Haslet Road at Buffalo Creek.

Issued in Austin, Texas, on August 26, 1996.

TRD-9612460
Robert E. Shaddock
General Counsel
Texas Department of Transportation
Filed: August 26, 1996

♦ ♦ ♦

Notice of Invitation: The Texas Department of Transportation (TxDOT) intends to engage an engineer, pursuant to Texas Government Code, Chapter 2254, Subchapter A, and 43 TAC §§30-9.40, to provide the following services. The engineer selected must perform a minimum of 30% of the actual contract work to qualify for contract award.

RFP Number 20-7RFP5001: For engineering services of two professional engineering firms as prime providers to provide scour evaluations on those bridges with susceptibility to scour and make recommendations for counter measures for the Beaumont District. The work will be performed in Jefferson, Chambers, Liberty, Newton, Orange, Hardin, Jasper and Tyler Counties.

Deadline: A letter of interest notifying TxDOT of the provider's intent to submit a proposal will be accepted by fax at (409) 898-5801, or by hand delivery to TxDOT, Beaumont District Office, Attention: Liz Humphrey, 8350 Eastex Freeway, Beaumont, Texas 77708, or by mail to P. O. Box 3468, Beaumont, Texas 77704-3468. Letters of Interest will be received until 5:00 p.m. on Friday, September 13, 1996. The letter of interest must include the engineer's firm name, address, telephone number, fax number, name of engineer's contact person and refer to RFP Number 20-7RFP5001. Upon receipt of the letter of interest a Request for Proposal packet will be issued. (Note: Written requests either by mail, hand delivery or fax, will be required to receive Request for Proposal packet. TxDOT will not issue Request for Proposal packet without receipt of letter of interest.)

Proposal Submittal Deadline: Proposals for RFP Number 20-7RFP5001 will be accepted until 5:00 p.m. on Friday, September 27, 1996 at the TxDOT Beaumont District Office mentioned addresses.

Issued in Austin, Texas, on August 26, 1996.

TRD-9612461
Robert E. Shaddock
General Counsel
Texas Department of Transportation
Filed: August 26, 1996

♦ ♦ ♦

Notice of extension of deadline to receive proposals. The Texas Department of Transportation published in 21 TexReg 7503, August 6, 1996 intention to engage an engineer pursuant to Texas Government Code, Chapter 2254, Subchapter A, to perform a preliminary feasibility study for the proposed Camino Colombia Toll road. Eight proposers submitted letters of interest and were accordingly mailed copies of the Request For Proposal (RFP). Due to unforeseen delays in the US Postal Service proposals could not be timely submitted before the 5:00 p.m. Friday, August 23, 1996 original deadline, and TxDOT finds that all interested proposers did not have a reasonable ability to submit a proposal. Therefore, for the eight firms having RFP's, TxDOT extends the deadline for the submission of proposals to 5:00 p.m. Friday, September 6, 1996. To be considered, proposals must be received prior to that time by Frank J. Smith, Director,

Budget and Finance Division, TxDOT, 125 East 11th Street, Austin, Texas.

Issued in Austin, Texas, on August 26, 1996.

TRD-9612459
Robert E. Shaddock
General Counsel
Texas Department of Transportation
Filed: August 26, 1996

♦ ♦ ♦

Texas Youth Commission

Legal Services Sought

The Texas Youth Commission (TYC) is seeking legal services.

Service: (1) Preparation for and legal representation of TYC indigent youth at TYC due process administrative hearings, including parole revocation and/or reclassification hearings conducted during the term of the contract. (2) Multiple hearings are set daily, state wide. (3) Hearings should be held within ten days of detention of youth or, in some situations, ten days from submission of request for hearing.

Compensation: (1) Total cost of legal services, based on an hourly rate not to exceed $50.00 and a cap not to exceed $150.00 per hearing. (2) Only expenses involving pre-approved travel will be reimbursed for out-of-county travel and only at the state rate and according to state travel regulations. (3) Non-exclusive, multiple awards within the same service area will be granted. Note: Average length of a hearing is approximately 3.4 hours. The estimated average number of hearings for FY'97 is 60 hearings per month statewide.

Area: Normally hearings are conducted at local juvenile detention or TYC facilities in the county where the offense occurred.

Time: Appointed by TYC as needed on a daily basis.

Qualifications: (1) Licensed in the State of Texas - mandatory. (2) Demonstrated competence in the areas of administrative hearings, criminal law, and civil procedure - mandatory. (3) Two years experience in the required areas of competence - preferred. (4) Must be able to provide services with three days notice. (5) Must have an office within the surrounding area in which services are delivered. (6) Must be willing to sign an open-ended contract.

Selection for Appointment Criteria: (1) 50% Cost (2) 50% Experience

Any one wishing to respond to this proposal, should provide to W.J. Ham, Staff Attorney, your fee scale and a description of how you meet the requirements listed above. Responses will be considered if mailed by September 30, 1996. Mr. Ham's address is P.O. Box 4260, Austin, Texas 78765, phone number is (512) 483-5188, fax number is (512) 483-5166

Issued in Austin, Texas, on August 23, 1996.

TRD-9612380
Steve Robinson
Executive Director
Texas Youth Commission
Filed: August 23, 1996

♦ ♦ ♦

Texas Register
Services

The *Texas Register* offers the following services. Please check the appropriate box (or boxes).

Texas Natural Resource Conservation Commission, Title 30

❑ **Chapter 285** $20 ❑ update service $15/year *(On-Site Wastewater Treatment)*
❑ **Chapter 290** $20 ❑ update service $15/year *(Water Hygiene)*
❑ **Chapter 330** $45 ❑ update service $15/year *(Municipal Solid Waste)*
❑ **Chapter 334** $35 ❑ update service $15/year *(Underground/Aboveground Storage Tanks)*
❑ **Chapter 335** $25 ❑ update service $15/year *(Industrial Solid Waste/Municipal Hazardous Waste)*

Update service should be in ❑ printed format ❑ 3 1/2" diskette ❑ 5 1/4" diskette

Texas Workers Compensation Commission, Title 28

❑ Update service $25/year

Texas Register Phone Numbers

Documents	(512) 463-5561
Circulation	(512) 463-5575
Marketing	(512) 305-9623
Texas Administrative Code	(512) 463-5565

Information For Other Divisions of the Secretary of State's Office

Executive Offices	(512) 463-5701
Corporations/	
Copies and Certifications	(512) 463-5578
Direct Access	(512) 463-2755
Information	(512) 463-5555
Legal Staff	(512) 463-5586
Name Availability	(512) 463-5555
Trademarks	(512) 463-5576
Elections	
Information	(512) 463-5650
Statutory Documents	
Legislation	(512) 463-0872
Notary Public	(512) 463-5705
Public Officials	(512) 463-5552
Uniform Commercial Code	
Information	(512) 475-2700
Financing Statements	(512) 475-2703
Financing Statement Changes	(512) 475-2704
UCC Lien Searches/Certificates	(512) 475-2705

Please use this form to order a subscription to the *Texas Register*, to order a back issue, or to indicate a change of address. Please specify the exact dates amd quantities of the back issues required. You may use your VISA or Mastercard. All purchases made by credit card will be suject to an additional 2.1% service charge. Return this form to the Texas Register, P.O. Box 13824, Austin, Texas 78711-3824. For more information, please call (800) 226-7199.

❒ **Change of Address**

❒ **Back Issue**
_____ Quantity
Volume _____,
Issue # _____
(Prepayment required for back issues)

❒ **New Subscription (Yearly)**

Printed ❒ $95

Diskette
❒ 1 to 10 users $200
❒ 11 to 50 users $500
❒ 51 to 100 users $750
❒ 100 to 150 users $1000
❒ 151 to 200 users $1250
More than 200 users--please call

Online BBS
❒ 1 user $35
❒ 2 to 10 users $50
❒ 11 to 50 users $90
❒ 51 to 150 users $150
❒ 151 to 300 $200
More than 300 users--please call

NAME _____

ORGANIZATION_____

ADDRESS _____

CITY, STATE, ZIP _____

Customer ID Number/Subscription Number _____
(Number for change of address only)

❒ **Bill Me** ❒ **Payment Enclosed**

Mastercard/VISA Number _____

Expiration Date _____ Signature _____

Please make checks payable to the Secretary of State. Subscription fees are not refundable.
Do not use this form to renew subscriptions.

_____
_____
Periodical Postage

PAID

Austin, Texas
and additonal entry offices
_____
_____